UNDERSTANDING HOPES AND FEARS OF PATIENTS UNDERGOING SURGERY FOR PELVIC ORGAN PROLAPSE:

A dissertation submitted to the Tamil Nadu Dr. M.G.R. Medical University, Chennai, in partial fulfillment of requirements for the degree MS (Branch II) in Obstetrics & Gynaecology, *April 2014*

CERTIFICATE :

This is to certify that the dissertation entitled **" Understanding the hopes and fears of patients undergoing surgery for pelvic organ prolapse"** is the bonafide work of Dr. Beena K. towards the MS Branch II (Obstetrics and Gynaecology) Degree Examination of the Tamil Nadu Dr. M.G.R. Medical University, Chennai to be held in April, 2014

Signatres :

Guide : Dr. Lilly Varghese,

Professor, Obstetrics and Gynaecology Unit 11

Head of Department : Dr. Abraham Pedicayil,

Professor,

Head of Department,

Obstetrics and Gynaecology, Unit 1

Prinicipal :

Acknowledgements :

I would like to firstly thank my Lord God Almighty for helping me through this task. I express my deep sense of gratitude to my guide, Dr. Lilly Varghese, Professor in Obstertrics and Gynaecology Department, Unit II for all her encouragement and expert guidance. I am extremely grateful to, Dr. Aruna Kekre, Professor and Head of Department of Obstetrics and Gynaecology, Unit II, Dr. Jaya Prakash Mulliyal, Rtd. Professor in Clinical Epidemiology and Dr.Shantidani Minz, Professor in Department of Community Health for their guidance. I also express my heartfelt gratitude to my statistician Mrs. Grace Rebekah, Department of Biostatistics for her efforts in helping me through this learning process.

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UNDERSTANDING THE HOPES AND FEARS OF PATIENTS UNDERGOING SURGERY FOR PELVIC ORGAN PROLAPSE : Introduction : Pelvic floor dysfunction consists of a wide range of conditions like urinary incontinence, fecal incontinence, pelvic organ prolapse, sexual dysfunction and chronic pelvic pain. But of these the three most important and frequently encountered are urinary incontinence, fecal incontinence and pelvic organ prolapse. It is a common condition occurring in 30% of women attending gynaecology OPD and 50% of women over 50 years old(1) The impact of the pelvic floor dysfunction is manifested as decrease in the quality of life of patients and the economic impact of the treatment rather than...

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November 23, 2012

Dr. Beena. K
PG Registrar
Department of OG
Christian Medical College
Vellore 632 002

Sub: **FLUID Research grant project NEW PROPOSAL:**
Understanding the hopes and fears of patients undergoing surgery for pelvic organ prolapse a qualitative study in South India.
Dr. Beena K, PG Registrar, OG, Dr. Lilly Varghese, OG, Dr. Aruna Kekre, OG, Dr. Shantidani Minz, Community Health, Gifta Priya Manohari, Community Health.

Ref: IRB Min. No. 7970 dated 08.09.2012

Dear Dr. Beena. K,

The Institutional Review Board (Blue, Research and Ethics Committee) of the Christian Medical College, Vellore, reviewed and discussed your project entitled "Understanding the hopes and fears of patients undergoing surgery for pelvic organ prolapse a qualitative study in South India" on September 9, 2012.

The Committees reviewed the following documents:

1. Format for application to IRB submission
2. Information Sheet and Informed Consent Form (English, Tamil, Hindi, Telugu and Bengali)
3. Cvs of Drs. Beena K, Lilly Varghese, Aruna Kekre, Shantidani Minz, Gifta Priya Manohari
4. A CD containing documents 1 - 3

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We approve the project to be conducted as presented.

The Institutional Ethics Committee expects to be informed about the progress of the project, any serious adverse events occurring in the course of the project, any changes in the protocol and the patient information/informed consent. And on completion of the study you are expected to submit a copy of the final report.

A sum of Rs 1,500/- (Rupees One Thousand Five hundred only) will be sanctioned for 10 months.

Yours sincerely

Dr Nihal Thomas
MBBS MD MNAMS DNB (Endo) FRACP (Endo) FRCP(Edin)
Secretary (Ethics Committee)
Institutional Review Board

Dr. Nihal Thomas
Secretary (Ethics Committee)
Institutional Review Board

cc: Dr. Lilly Varghese, Department of OG

TEL : 0416 - 2284294, 2284202 FAX : 0416 - 2262788, 2284481 E-mail : research@cmcvellore.ac.in

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Introduction :

Pelvic floor dysfunction consists of a wide range of conditions like urinary incontinence, fecal incontinence, pelvic organ prolapse, sexual dysfunction and chronic pelvic pain. But of these the three most important and frequently encountered are urinary incontinence, fecal incontinence and pelvic organ prolapse. It is a common condition occurring in 30% of women attending gynaecology OPD and 50% of women over 50 years old(1) The impact of the pelvic floor dysfunction is manifested as a decrease in the quality of life of patients and the economic impact of the treatment rather than increase in morbidity or mortality by the prolapse per se. It has been found that women with pelvic organ prolapse have decrease in self image, quality of life and spend an average of 750$ per year for treatment(2,3) Traditionally, the definitive treatment for pelvic organ prolapse has been surgical correction seeking to restore normal anatomy and function of the affected organs. However, this concept has been challenged over the past decade. And as of today, there is no consensus regarding the best method of assessing treatment outcome for patients with pelvic floor dysfunction. Barber et al in their study found that, the success rates for pelvic organ prolapse surgery varied widely (19.2-97.2%) depending on the definition used for treatment success(4) . They found that 71% of their patients considered their surgery “very successful” and 85.2% considered themselves “much better” than before surgery. However defining success as ‘all anatomical supports to be proximal to the hymen’ showed the lowest success rates (19.2-57.6%).(4) A survey done in 2002 by Tincello et al among patients, Medical practitioners and nurses found that improvement in quality of life and subjective measures were the two most popularly used outcome measures in urogynecology(5)There has been no consensus regarding the best method of outcome assessment for pelvic organ prolapse surgery, but the achievement of patient oriented goals has gained importance over the years(2,6,7).

Patient's expectations are shaped by their symptoms, personal experiences, social circumstances and experience of the treating clinician. Attaining anatomical restoration of the pelvic floor may not be a complete 'cure' in itself if their initial expectations are not met at the end of the surgery or if new symptoms related to urinary, sexual and bowel dysfunctions arise after surgery. Having 'unrealistic' expectations prior to surgery will lead to dissatisfaction and absence of 'cure' for that particular patient(6).

Over the past decade various international organizations like The International Continence Society, The National Institute of Health (NIH) and World Health Organization's International Consultation on Incontinence have suggested recommendations for measuring outcome in patients with pelvic floor disorders. Various psychometric self administered questionnaires have been formulated and validated over the years for assessing disease specific symptoms and those for quality of life assessment with respect to urinary incontinence, colorectal and sexual function, and urogenital prolapse. But such disease-specific Qol questionnaires do not consider the expectations of individual patients and lack sensitivity to assess individual symptoms(8–14).

Although these condition specific QOL questionnaires have been widely used in other communities,for our Indian community, the relevance, the reliability and the ease of use of these disease specific quality of life questionnaires has not been validated. Many different languages are spoken in any given community set up. These variations make uniform assessment with a questionnaire validated in English a difficult task.

All these raised the question of which system of outcome measure may be the most feasible and appropriate for our community. It has been reported in studies done earlier that patient selected goals and their perception of the primary goal being the driving force for treatment decision. Our community has also been influenced by the changing trends of the 20^{th} century. The role of women in society and family are influenced by these changes. Do our women

need a different outcome measure for pelvic floor reconstructive surgery. Are their expectations met in undergoing the treatment offered? Which is a better outcome measure in our community? This study attempts to understand these queries from the patients perspective.

Aims and objectives of the study :

Aims:

1. To enlist the hopes and fears of our patients undergoing surgery for pelvic organ prolapse.
2. To measure the achievement of hopes and resolution of fears in a subset of patients willing for follow up post operatively either telephonically or in person, at 6 weeks and 3 months.
3. To look at the merits of our own study instrument developed at home compared to that of an available validated quality of life questionnaire.

Objectives :

Primary objective :

1. To enlist the hopes and fears of our patients undergoing surgery for pelvic organ prolapse in their own words.
2. To assess quality of life using validated POP questionnaires POPDI-20 and PFIQ-7.

Secondary objective :

1. To measure the achievement of hopes and resolution of fears in a subset of patients willing for follow up post operatively either telephonically or in person, at 6 weeks and 3 months.
2. To compare patient's perception of achievement of hopes and the resolution of fears with the results obtained for the validated questionnaire on quality of life.
3. To look at the merits of our own study instrument developed at home compared to that of a standardized questionnaire.

Literature review :

Contents :

Introduction :

Pelvic floor dysfunction includes a wide range of conditions like urinary incontinence, fecal incontinence, pelvic organ prolapse, sexual dysfunction and chronic pelvic pain. But of these the three most important and frequently encountered are urinary incontinence, fecal incontinence and pelvic organ prolapse. Pelvic organ prolapse (POP) is defined as “a bulge or protrusion of pelvic organs and their associated vaginal segments into or through the vagina”(15).

Incidence :

It is a common condition occurring in 30% of women attending gynaecology OPD and 50% of women over 50 years old(16). According to a study done by Oslen et al, in the United States there is a 11% lifetime risk for a woman to undergo a surgical procedure for pelvic organ prolapse or urinary incontinence and of these, nearly one third are repeat procedures (17). A study conducted in the United States, as a nationwide population based estimate for prevalence of pelvic floor disorders (urinary incontinence, fecal incontinence and pelvic organ prolapse) concluded that $1/4^{th}$ of all women and more than $1/3^{rd}$ of all older women had symptoms related to at least one of the three pelvic floor disorders. Their study showed that 9.7 % of women aged between 20 to 39 years had at least one pelvic floor disorder. This increased with age, reaching 36.8% among women aged 60 to 79 years and 49.7% among women aged older than or equal to 80 years(18)

A study was done in New Delhi from August 1996 to November 2000, in an urban slum covering a population of 3676. Out of the 380 women who were enrolled for the study and reported to the clinic, 60 (16%) of them had pelvic organ prolapse.(19) In South India the estimates of pelvic organ prolapse is found to be 3.4%.(20)

History :

Historically, prolapse has been first recorded in 2000BC. (21)Hippocrates and Gallen had mentioned pelvic organ prolapse in their writings. This suggests that unlike many other conditions and diseases in Medicine, this is not a problem of the new age. Ancient literature talks about women with prolapse being suspended by the feet for 24 hours and bounced up and down as part of the treatment followed by being bed ridden for 3 days with their legs tied together (22) In 98AD Soranus of Rome described removal of prolapse uterus when there was blackish discoloration of it. (22) The first reported surgical removal of the uterus for

prolapse was performed by a peasant woman named Faith Raworth described by Willouby in 1670 who was so distressed by it that she took a knife and cut the prolapse off by herself. (23) The understanding of this condition “pelvic floor dysfunction” has come a long way since then. It is a condition common to all classes of people, affecting women of varied age groups with a vast implication on their day to day living. All of which makes approach to this condition more challenging.

The causation of pelvic organ dysfunction is multifactorial. It occurs due to weakening of the supportive structures by either actual tears or neuromuscular dysfunctions or both.

Normal pelvic organ support:

The anatomic support for pelvic organs is by the interaction between the levator ani muscles and the connective tissue that attaches the pelvic organs to the bony pelvis.

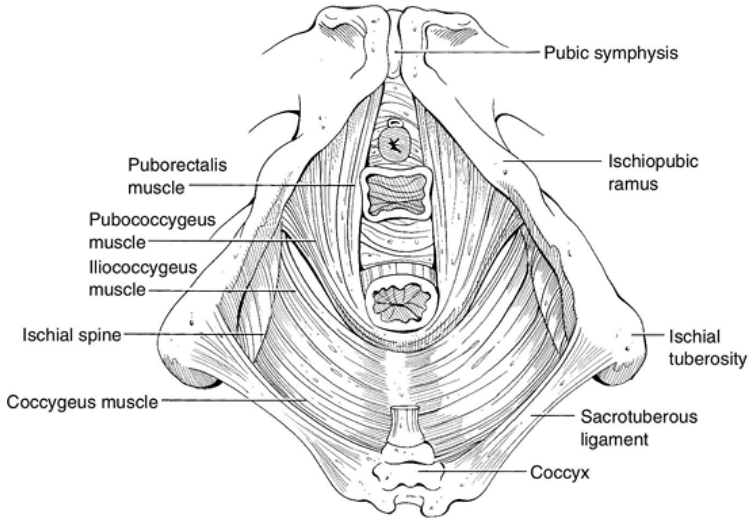


Figure 1 :Levator ani muscles inferior view

The levator ani muscle is the most important muscle of the pelvic floor. This consists of 3 main components : the pubococcygeus, puborectalis and illiococcygeus muscles.(24) The

pubococcygeus is further divided into 3 main components : the pubovaginalis, the puboanalis and the puboperineal muscles.

1. The *pubococcygeus muscle* also called the pubovisceral muscle, arises from the inner surface of the pubic bone and gets inserted to the coccyx posteriorly. During its course the muscle is inserted to the walls of the pelvic viscera. The pubovaginalis, puboperinealis and puboanalis are portions of the muscle that attaches respectively to the lateral walls of the vagina, the perineal body and the anus at the groove that lies between the external and internal anal sphincters.(25–27)
2. The *puborectalis muscle* fibres form a 'U' shaped sling. It arises on either side from the inner surface of the pubic bone and runs around the anorectal junction forming a sling, thereby drawing the anorectal junction close to the pubic bone on contraction.
3. The *iliococcygeus muscle* forms the most posterior portion of the levator ani muscle. It arises from the arcus tendenius levator ani and the ischial spines. The muscle fibres join those form the opposite side at the midline forming the iliococcygeal raphe and attaches to the coccyx.

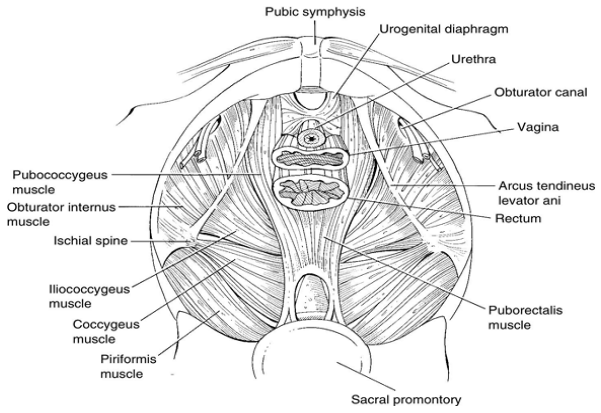


figure 2 : superior view of muscles of the pelvic floor:

The levator ani muscle therefore forms a broad, curved sheet of muscle extending all the way from the pubic bone anteriorly to the arcus tendenius laterally upto the ischial spines and

inserting into the central tendon of the perineum, the wall of the anal canal, the anococcygeal ligament, the coccyx, and the vaginal wall. It is perforated on its way by the vagina, urethra and the anal canal.

The muscle levator ani lies in a constant state of contraction thereby supporting the pelvic organs against the intra abdominal pressure. This helps the pelvic ligaments and fascia to be protected from excessive strain. This constant state of contraction draws the distal parts of the urethra, vagina and rectum towards the pubic bone keeping the urogenital hiatus closed.(28)

Pelvic Connective tissue : This consists of ligaments and fascia. DeLancey described three levels of connective tissue supports that are involved in Pelvic Organ Prolapse(29)

1. Cervical and upper vaginal support
2. Mid-vaginal support
3. Distal vaginal support

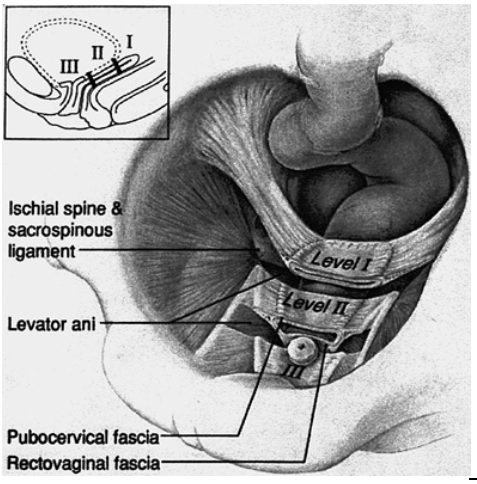


figure 3: De Lancey's levels of pelvic connective tissue support:

1. *Cervical and Upper vaginal support :* This forms level I of support. It consists of the parametrium and the upper paracolpium.

The parametrium refers to the perivascular connective tissue condensation that attaches the uterus to the posterolateral pelvic wall. This consists of the cardinal or transverse cervical or Mackenrodt's ligaments and the uterosacral ligaments(30,31).

Clinical significance : This provides support to the vault after hysterectomy. Therefore, defect of level 1 support leads to cervical and post-hysterectomy apical (vault) prolapse. Recent studies have shown correlation between supports of the anterior and apical compartments. Thereby, proving that defects in the apical support system can also lead to development of cystoceles(32,33).

2. *Mid-vaginal support :* This forms the level II support. It consists of the lateral attachments of the mid portion of the vagina to the pelvic walls. These lateral attachments of the anterior vaginal wall are the arcus tendineous fascia pelvis and the medial aspects of the levator ani muscles.

   Clinical significance : Defects in this level of support system leads to anterior vaginal wall prolapse and SUI (stress urinary incontinence) (34).

3. *Distal vaginal support :* This forms the level III support system. At this level (the distal 1/3rd) the vagina is directly attached to the surrounding structures. Anteriorly the vagina is attached to the urethra, laterally it is attached to the perineal membrane and the pubovaginalis muscle, and posteriorly it is attached to the perineal body. This level of support system is the strongest of the three.

Clinical significance : Defects in this support system leads to distal rectocele and perineal descent.

Delancey 's levels of vaginal support :

Level of support :	Supporting structures :	Result of defect :

Level 1 : cervical and upper vaginal support	Parametrium (uterosacral and Mackenrodt's ligaments) and upper paracolpium	1. Vault prolapse 2. Cervical descent 3. cystoceles
Level II : Mid – vaginal support	Arcus tendineous , medial aspects of levator ani muscles	1. anterior vaginal wall prolapse 2. SUI
Level III : Distal- vaginal support	Direct attachment to surrounding structures	Distal rectocele and perineal descent

Table 1: De lanceys levels of pelvic connective support

Pelvic floor dysfunction :

This includes a spectrum of problems pertaining to female pelvic organs. It consists of urinary incontinence, fecal incontinence, pelvic organ prolapse, sensory and emptying problems of the lower urinary tract, defecation problems, chronic pelvic pain and sexual dysfunction.

Pelvic organ prolapse :

Definition : The International Continence Society has defined Pelvic Organ Prolapse as the descent of 1 or more segments of : the anterior vaginal wall , the posterior vaginal wall or the apex of the vagina or vault(35).

Predisposing factors :

Pelvic Organ Prolapse has a multifactorial etiology. The various risk factors can be categorized into following groups :(1)

1. Predisposing factors
2. Inciting factors
3. Promoting factors
4. Decompensating factors

POP due to its complex etiology has various factors leading to its development. These multiple factors can be classified into the various above mentioned categories. However, one factor can fall into multiple categories.

1. Predisposing factors : These are certain factors that are inbuilt in the individual that predispose them to POP formation. Eg : race, neurological and muscular abnormalities and connective tissue makeup. These factors are inbuilt in the individual and therefore cannot be altered. Race was one of the predictive factors for POP. A study performed among comparable groups of Caucasian and African American populations found racial differences with regards to urethral closure pressure, cytometric capacity and therefore the number of patients affected by stress urinary incontinence and detrussor instability(36) A study performed among Asian and Caucasian women showed stronger pelvic floor ligaments and lesser pelvic organ mobility of the anterior and posterior compartments as compared to Caucasian women(37). Connective tissue disorders such as Marfan syndrome and Ehlers Danlos syndrome are associated with an increased risk of pelvic organ prolapse(38).

2.Inciting factors: These are the factors that can be modified. But very often these are the factors that cannot be avoided. They are as child birth, pelvic surgery and radiation. These lead to injury to pelvic nerves and muscles and can therefore lead to laxity of the pelvic floor. This in turn predisposes to development of pelvic organ prolapse.

3. Promoting factors: They are the group of factors that are easily modifiable. However, the effect of modifying them on the development of prolapse is uncertain. They are chronic constipation, obesity, Diabetes Mellitus, occupations that involve lifting of heavy weights (manual laborers, factory workers, homemakers), athletes, smoking, tea and coffee intake. There are certain drugs that are also considered to contribute in the development of prolapse. Obesity has also been identified as one of the promoting factors in development of prolpase. Athletes were also found to have an increased predisposition for development of prolapse than the general population due to increase in bladder neck descent and greater genital hiatal area.(39,40)

Smoking has also been reported to be a promoting factor in the devolpment of prolapse. Although the mechanism of its effect is not clearly known**.** (41)

There are certain drugs that can promote development of incontinence. They are ACE inhibitors, antipsychotics, antidepressants, benzodiazepines and alpha adrenergics.

Caffeine intake has been associated with 2.5 times increased risk of detrusor overactivity .(42) Another study that looked at association between lifestyle and development of prolapse reported that, it was tea and not caffeine that was a promoting factor.

4 . decompensating factors : These are factors that by can decompensate a well compensated pelvic floor, thereby, predisposing to the development of prolapse. For eg aging, delirium, confusion, dementia. These changes in mental status can lead to functional disability in the individual. They can therefore present with episodes of urinary or fecal incontinence.

Pathophysiology of POP:

With improved understanding of the pathophysiology of POP, it is clearly evident that it is multifactorial in its etiology. Studies have proven that vaginal deliveries and increase in age are the two most important factors involved in POP(43) .

There have been various theories hypothesized in the occurrence of pelvic organ prolapse. Following are some of the widely accepted theories :

1. *Failure of pelvic organ support* –effect of aging and childbirth . During the process of childbirth the levator ani muscles undergo direct or denervation injury that leads to pelvic organ prolapse later. This finally leads to loss of tone in the pelvic floor muscles causing widening of the genital hiatus and thereby leading to prolapse of pelvic organs.(44–47)

   However there have been various studies over the years challenging the above hypothesis. They are histomorphological disapproving of denervation and atrophic features in the levator ani muscles and the difference in the nerve supply of the levator ani muscles as compared to the nerve that is damaged during childbirth.(48–52)

   But biopsies taken from the levator ani muscle of women with stress urinary incontinence and pelvic organ prolapse showed features of prolonged denervation resulting in both neurogenic and myopathic alterations.(53,54)

   The effect of age induced change in the volume and function of striated muscle was also studied. Study done in women with POP of various age groups found substantial morphologic and biochemical changes among the age groups suggesting that aging does contribute to failure of pelvic organ support.(55) Another study looked at effect of age on the various points in POPQ (pelvic organ prolapse quantification system)

among women with symptomatic prolapse and found that increase in age had a progressively worsening effect (56)

2. *Role of connective tissue in pelvic organ support :* There has been several studies looking at the role of various connective tissue segments and ligaments in the pelvis with the occurrence of POP. Following is a list of them:

   a. Bony pelvis : It has been hypothesized that women with wider pelvic dimensions have greater risk for POP.(57,58)

   b. Arcus tendineous fascia pelvis and arcus tendineous levator ani : these two facial condensations form strong structural support to pelvic organs. The arcus tendineous levator ani is a condensation of connective tissue from where the iliococcygeus and pubococcygeus muscles derive their origin. The arcus tendineous fascia pelvis is a visceral connective tissue condensations that envelops the anterior and posterior vaginal walls anchoring it to the lateral pelvic walls. It has been hypothesized that damage to the arcus tendineous fascia pelvis by overstretching or tearing during the process of vaginal delivery can lead to development of POP.

   c. Uterosacral ligaments: This provides support to the pelvic organs (uterus, cervix and upper vagina) by suspending them to the dorsal body wall. Various studies have shown that in women with pelvic organ prolapse as compared to controls these ligaments were found to have areas of decreased smooth muscle and increase of apoptotic cells.(59) Study of the genetic expression in these ligaments suggested that women with POP had variation in the gene expressions in these ligaments that led to alteration in the healing mechanisms within the tissue. (60)

   d. Vaginal wall connective tissue : The connective tissue of the vagina suspends it to the arcus tendineous fascia pelvis , the superior fascia of levator ani, the perineal

membrane and perineal body. Weakening of this connective tissue further can lead to POP.

e. Vaginal wall collagen content : Connective tissue consists of collagen and elastin. Over the years this has been extensively studied. As of date there is evidence to suggest that in women with POP there is increased synthesis of collagen in the vaginal wall. But the newly formed collagen is immature less durable as compared to the mature collagen that is of better tensile strength and durability. (61–63)

f. Vaginal wall smooth muscle composition : the normal vaginal wall is composed of three layers : vaginal mucosa, a fibroelastic muscularis layer and the adventitious layer that consists of loose areolar tissue, neurovascular bundle and elastic fibers. Studies have shown that the normal vaginal wall consists of smooth muscle that comprises 45% of the cross sectional area but in women with POP this is reduced to almost 22%. (64) The distribution of nerve bundles also varies in the vaginal wall of women with and without POP. In normal vaginal wall there are large and numerous nerve bundles whereas in women with POP the vaginal wall consists of thinner and fewer nerve bundles. (65)

g. Phenotypic abnormality of smooth muscle cells of the vaginal wall : Caldesmon and smooth muscle myosin heavy chain are two molecular markers of smooth muscle. It has been proven that women with POP have a disproportionate representation of these markers in the smooth muscle of the vaginal muscularis layer suggesting a phenotypic abnormality in the vaginal wall smooth muscle cells of these women.(66)

h. Protease activation in the pelvic floor connective tissue : It has been shown that uninhibited protease activity leads to the onset and progression of any degenerative pathology. There are various types of matrix metalloproteinases (MMPs). Of these it

has been seen that MMP9 and pro-MMP2 have been reported to occur in the vaginal wall of women with POP. (67,68)

Therefore to summarize, the various studies done over the years have shown that the vaginal wall in a women with pelvic organ prolapse has certain inherent abnormality in its fibromuscular composition. However, it has not been proven whether these changes are as a result of the mechanical tension in these tissues due to prolapse or if these changes in the fibromuscular composition are the reason for the prolapse. But epidemiological studies do indicate that vaginal birth and aging are the two most important factors in the pathogenesis of pelvic organ prolapse. But there is no proven data regarding the specific effects caused by pregnancy, child birth and aging on the pelvic floor support mechanisms, which later leads on to POP.

Evaluation of women with pelvic floor dysfunction :

Pelvic floor disorders are a common spectrum of conditions that accounts for about 30% of patients attending Gynecology OPD and 50% of patients over 50 years of age.(16) According to a study done by Oslen et al, there is a 11% lifetime risk for a women to undergo surgery for either pelvic organ prolapse or for urinary incontinence. (69) Although pelvic floor dysfunction is generally not a life threatening condition, this disorder has a great impact on a women's life. This condition although has no associated increase in morbidity or mortality, it greatly affects the quality of life, emotional well being and self image, apart from being an economic burden. (3,70)

Pelvic floor dysfunction includes a wide range of conditions like urinary incontinence, fecal incontinence, pelvic organ prolapse, sexual dysfunction and chronic pelvic pain. But of these, the three most important and frequently encountered are urinary incontinence, fecal incontinence and pelvic organ prolapse.

Therefore during evaluation of a patient with pelvic floor dysfunction the clinician needs to address these areas of urinary, fecal and sexual dysfunction, pelvic pain and POP per say.

Symptoms :

Women with POP can either be symptomatic or asymptomatic. Symptomatic POP is the least common of all the pelvic floor dysfunctions accounting for about 2.9-6%. (18,71) Women with POP can present with any of the following complaints :

1. Seeing or feeling a vaginal bulge
2. The sensation of a vaginal bulge or protrusion
3. Inconvenience while sitting
4. Bulge rubbing against their undergarments
5. Inability to use tampons

Of the above mentioned symptoms, the two most frequently reported are the feeling or seeing a vaginal bulge and the sensation of a vaginal bulge or protrusion.(72,73)

Urinary symptoms cannot always be attributed to the prolapse. Some of the following urinary symptoms may be due to urethral kinking.

1. Urinary hesitancy
2. Poor stream of voiding
3. Incomplete voiding
4. Need to manually reduce the vaginal bulge to void (splinting)
5. Need to push on the lower abdomen to void (Crede maneuver)
6. Positional changes made to void
7. Post void urinary dribble
8. Urinary urgency

9. Increased urinary frequency
10. Urinary urge incontinence
11. Stress urinary incontinence
12. Urinary retention

Population based studies have shown the prevalence of urinary incontinence alone to range from 15%-28% of which 50% of them have mixed urinary incontinence, 15%-33% have stress urinary incontinence and 13% have urge incontinence.(71,74)

Similarly defecatory dysfunction can also be present and women with POP may encounter the following.

1. Straining to defecate
2. Incomplete defecation
3. Need for digital evacuation
4. Incomplete evacuation
5. Need to push on the posterior vaginal wall for defecation (splinting)
6. Fecal urgency
7. Fecal incontinence (liquid or formed stool)
8. Incontinence to flatus

In population based studies fecal incontinence prevalence ranges from 7.2%-9%.(18,75)

Sexual dysfunction is also known to occur among patients with POP. The common sexual complaints are abstainance due to dyspareunia , decrease in libido, sexual dissatisfaction.(76,77) Sexual dysfunction is one of the factors that influence the quality of life.

Pelvic pain is another commonly encountered complaint among women with POP. The other nonspecific complaint that occurs among these women is low back ache. Pelvic floor muscle spasm may be perceived as pelvic pain, heavy feeling in the pelvic area, pain during defecation, dyspareunia and low back pain. Low back ache is also said to occur due to stretching of the uteroscaral ligaments as the cervix descends Many Of these symptoms worsen on exertion and decreases on rest.

Abnormal vaginal discharge and bleeding are the other associated problems in POP. The vaginal discharge is generally mucoid and occasionally can be blood stained venous stasis and edema in the cervix and vagina can lead to development of decubitus ulcers. Ulceration and trauma on the cervix can also lead to bleeding.

Examination :

General examination : This consist of assessing the nutritional status and assessing for any predisposing factors for POP. The following need to assessed : BMI (body mass index), nutritional status, mobility of joints, features suggestive of connective tissue disorders. The abdomen needs to be examined carefully for ascites, abdominal masses, inguinal and femoral hernia orifices.

a. *Neurological examination :* The spectrum of symproms associated with POP especially the urinary and bowel complaints can be associated in women with neurological abnormalities. It is therefore important to perform a basic minimal neurological assessment in these women.They are evaluation of mental status (MMSE), sensory and motor functios, strength of levator ani muscles, anal and bulbocavernous and deep tendon reflexes.

Evaluation of mental status: The Mini Mental State Examination consists of 11 questions that helps in assessing the cognitive function of the patient. It has a maximum score of 30. Score of <= 23 indicates cognitive impairment. (78)

Sensory functions : Assessment of the lumbosacral dermatomes helps in identifying peripheral neuropathy and differentiating between central and peripheral neuropathies. The various dermatomes that are examined are eg. the mons pubis and upper labia majora (L1,L2),the front of knees (L3,L4), the lateral aspect of foot (S1) and the perineal and perianal skin (S2,S3)

Motor sensation : The motor function of the lumbosacral cord is examined by testing the various groups of muscles in the lower extremities and the pelvic floor and grading it from 0[No muscle movement] to 5[Normal strength]according to the Oxford scale. Eg flexion of the hip joint (L2,3), extension of knee joint (L 3,4), dorsiflexion of ankle joint (L4,5) and plantar flexion of ankle joint (S1,2)

Strength of the levator ani muscles is also assessed and graded according to the modified Oxford scale or the Kegel's from 0-5. For evaluating the strength of the levator ani muscles the women is examined in the dorsal position. The levator ani can be grasped between the two fingers of the examiner by palpating the vaginal wall at 5 O'clock and 7 O'clock positions, about 2-4 cm away from the hymenal edge and the women is asked to contract the muscle.(79) The strength of the muscle is then graded from 0-5 as follows:

Grade	Description according to Modified Oxford Scale	Description according to the Kegel's scale
0/5	No discernible pelvic floor muscle contraction	Unable to contract

1/5	A flicker, weak contraction, pushing under the examining finger	Trace contraction, <2 seconds
2/5	A weak contraction , an increase in the tension in the muscle without any discernible lift or squeeze	Weak contraction, >3 seconds
3/5	Moderate contraction, some degree of lifting of the posterior vaginal wall with in drawing of the perineum	Moderate contraction 4-6 seconds, posterior elevation of fingers repeated 3 times
4/5	A good contraction, elevation of the posterior vaginal wall against resistance and in drawing of the perineum	Strong contraction,7-9 seconds, posterior elevation of fingers repeated 4-5 times
5/5	Strong contraction, strong resistance can be given against elevation of the posterior vaginal wall that causes approximation of two fingers kept laterally in the vagina	Very strong contraction, >10 seconds posterior elevation of fingers repeated 4-5 times

Table 2: grading of strength of muscles by Modified Oxford scale and Kegel's scale

The integrity of the pudendal nerve is evaluated by performing the anal wink reflex and the bulbocavernous reflex.

The anal wink reflex : This is performed by stroking the skin in the perianal region. Positive reflex is when this causes the external anal sphincter to contract.

The bulbocavernous reflex: This is performed by gently tapping or squeezing the clitoris. This leads to reflex contraction of the bulbocavernosis and the ischiocavernosis group of muscles.

These reflexes are generally absent in women with pudendal nerve damage. But 10% of women with normal neurological functions can also have absence of these reflexes.

Deep tendon reflexes : Knee jerk is checked as this helps in differentiating level of the neurological defect. Hyperreflexia is seen in women with upper motor neuron lesions where as absent or sluggish reflexes are seen in women with lower motor neuron lesions.

Pelvic examination : Pelvic examination is performed to gather information regarding the following :

a. Confirm the diagnosis of POP
b. Stage of POP
c. Decide treatment options

Examination is performed with the patient in dorsal lithotomy position while performing maximal vulsalva maneuver. There have been studies that show that there is no significant difference in findings by variation in examining position (standing or dorsal lithotomy positions) or the time of day of performing the examnination (morning or mid afternoon) (80,81)

Classification POP:

Over the years several classification systems have been developed as mentioned below.

a. Uterovaginal prolapse classification

b. Shaw's classification

c. Baden Walker's classification

d. Pelvic organ prolapse quantification system POPQ

The *various terminologies* used in description of pelvic organ prolapse are :

1. *Anterior compartment defect :*

   Cystocele : descent of the bladder. Seen as a bulge in the upper 2/3rd of the anterior vaginal wall

   Urethrocele : descent of the urethra. Seen as a bulge in the lower 1/3rd of the anterior vaginal wall

2. *Middle compartment defect :*

   Cervical descent

   Vaginal vault descent (in post hysterectomised women)

   Enterocele : herniation of bowel and/or omentum. Seen as a bulge in the upper 1/3rd of the posterior vaginal wall

3. *Posterior compartment defect :*

   Rectocele : descent of the rectum. Seen as a bulge in the middle 1/3rd of the posterior vaginal wall

Deficient perineum : decrease in the distance between the posterior forchette and the anal verge

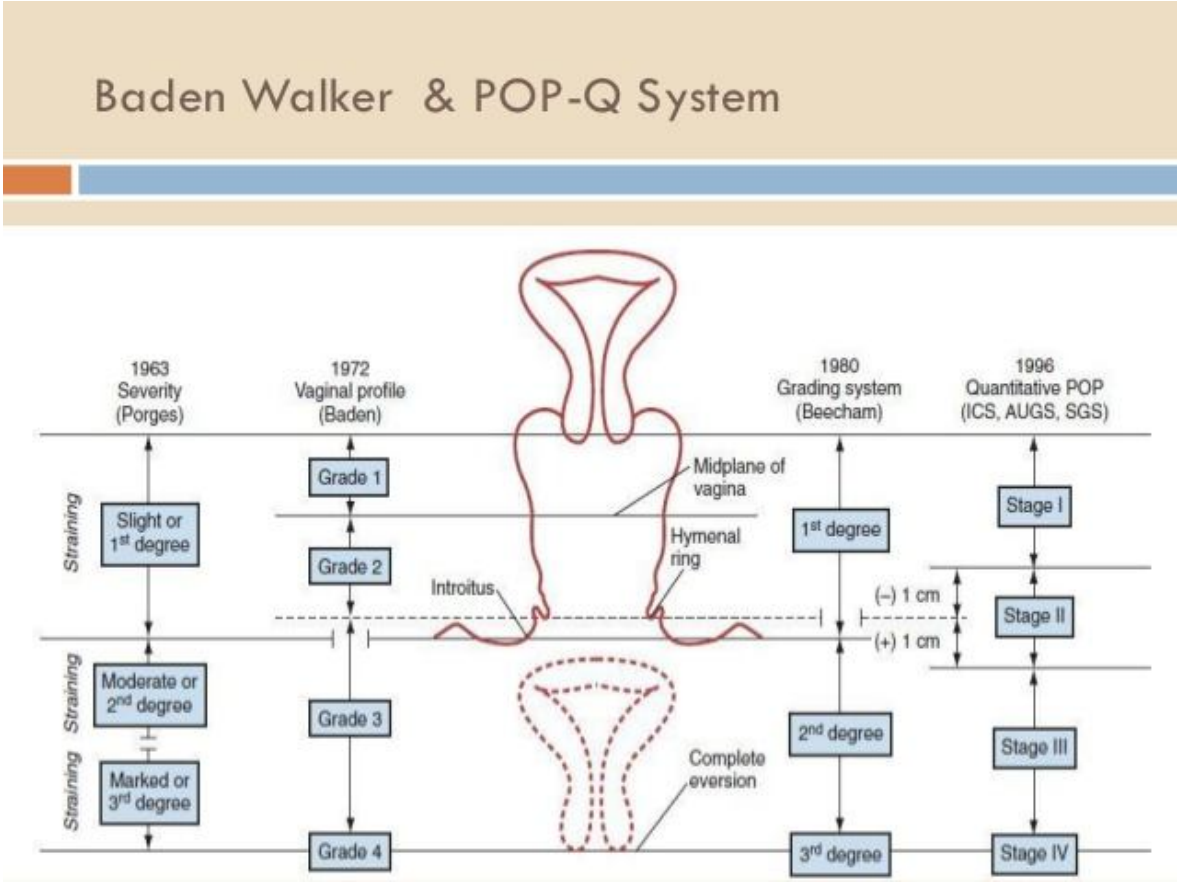


figure 4 : comparison of various classification systems for POP ref : evaluation of patients with urinary incontinence and pelvic organ prolapse:

<u>Shaw's classification :</u>

Normal : no descent. Cervix lies at the level of the ischial spines

First degree: descent of the cervix beyond the level of the ischial spines but still lying above the introitus

Second degree: descent of cervix upto the level of the introitus

Third degree: descent of cervix beyond the level of the introitus

Fourth degree / Procidentia : uterine fundus lying outside the level of the introitus

<u>Baden Walker's halfway system of grading :</u>

In this system of classification the hymen is taken as the reference point and each component is graded from 0-4 as follows:

t Various grades a with hymen as b the reference l point	Urethrocele, cystocele, prolapse and rectocele	Enterocele	Chronic pelvic laceration
e Grade 0	Normal	Normal ie. Maximum of 2cm of cul-de-sac between the posterior cervix and rectum	Normal ie. No more than just the laceration of the hymen
3 Grade 1 :	Descent halfway to hymen	Herniation of the cul-de-sac to 1/4th the distance to hymen	Laceration involving the anterior half of the perineal body
Grade 2 B	Descent upto hymen	Herniation of the cul-de-sac to ½ the distance to hymen	Laceration involving the perineal body but not the anal sphincter
a Grade 3 y	Descent halfway beyond the hymen	Herniation of the cul-de-sac to ¾ th the distance to hymen	Laceration involving the anal sphincter
d Grade 4 e t	Maximal descent, more than halfway beyond the hymen	Herniation of the cul-de-sac upto the level of the hymen	Laceration involving the anal mucosa

Table 3: showing Bayden Walker grading of POP

Ordinal Pelvic organ prolapse quantification system POP-Q:

The reason for the development of such several classification systems for POP itself suggests that each one of them have a lot of limitations. The limitations were lack of reproducibility, inaccurate quantification for scientific use and lack of specificity.

This was approved by the International Continence Society, the American Urogynecologic Society and the Society of Gynecologic Surgeons. This

system uses description of the prolapse in cm by 9 points measured on the vaginal wall and the perineal body. (82)These 9 points are represented in the form of a 3x3 grid as depicted below.

Aa – point on the anterior vaginal wall and 3 cm proximal to the urethral meatus	Ba- most dependant portion of the anterior vaginal wall measured from the hymen	C- the most distal portion of the cervix or the vaginal vault from the hymen
Gh – genital hiatus (distance from the external urethral meatus to the posterior hymenal remanant)	Pb- perineal body(distance from the posterior forchette to the middle of the anal opening)	Tvl – total vaginal length (distance from the hymen to the point D in a reduced prolapse)
Ap – point on the posterior vaginal wall and 3 cm proximal to the hymen	Bp – most dependant portion of the posterior vaginal wall measured from the hymen	D – position of the posterior vaginal fornix/ attachment of the uterosaccrals (absent in hysterectomised patients)

Table 4: the points in the ordinal POPQ staging

Staging of the POP-Q as follows :

Stage 0 – normal. i.e. Points Aa, Ba, Ap and Bp are all at -3 and points C and D are <= - (tvl-2)

Stage 1 – the most distal portion of the prolapse is > 1cm above the level of the hymen ie value <-1

Stage 2 – the most distal portion of the prolapse is <= 1 cm proximal or distal to the level of the hymen ie. >= -1 cm but <=+1 cm

Stage 3 – the most distal portion of the prolapse is >1cm beyond the level of the hymen but < 2m of the total vaginal length ie > +1 cm but < +(Tvl -2)

Stage 4 – complete eversion. The distal portion of the prolapse is at >= 2cm less than the total vaginal length ie. >=+(Tvl-2)

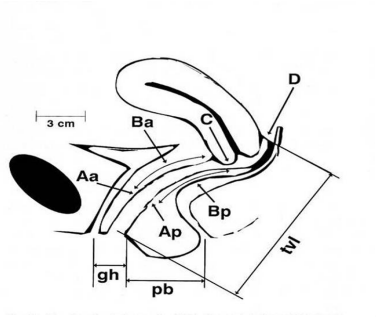


figure 5 : depiction of the 9 points of the POPQ claasification of POP

Treatment for pelvic organ prolapse:

History : the treatment for prolapse has evolved over the centuries. The era of prolapse treatment started with patients being suspended by the foot for 24 hours. (22)It evolved with the thought of it needing to be dealt with an iron rod by Rodericus Castro. During his time various substances like silver nitrate, nitric acid, hot metal and sulphuric acid were used for it.(22) The first documented hysterectomy was self performed by a women in her distress due to the prolapse.

The first hystetrectomy for POP was performed by Samuel Choppin of New Orleans in 1861 under anaesthesia and with aseptic precautions.(83) From the early 1800 onwards this field had seen a steady growth with introduction of various treatment modalities. By the beginning of the 20th century vast progress was being made in the field of medicine and anaesthesia. Side by side with these developments, there was also growing progress in Europe and America in surgical treatment options for prolapse. There was introduction of surgeries like colporrhaphy, cervical amputations, cervical ligament plications, colpocleisis and fixation of uterus to the abdominal wall. Since then there has been a steady progress in the treatment modalities for prolapse.

The management of POP depends on the following :

a. Age of patient
b. Desire to retain uterus
c. Fertility concerns
d. Degree of prolapse
e. Prior surgery for prolapse
f. Type of prolapse : anterior vaginal wall, posterior vaginal wall, uterovaginal
g. Associated stress urinary incontinence
h. Other comorbidities.

Currently, the treatment for pelvic organ prolapse can be broadly classified as follows:

1. *Conservative* – consisting life style modification, pelvic floor exercises and vaginal pessaries like Smith-Hodge and ring pessary.
2. *Surgical* – the aim is restoration of the normal anatomy and function. There are two broad classes of surgeries that can be performed.
    a. Reconstructive procedures
    b. Obliterative procedures

    Reconstructive procedures are again classified depending on the site of involvement.

    a. Anterior vaginal wall :
        i) Anterior colporrhaphy – plication of the pubovesicocervical fascia
        ii) Site specific repair - pubocervical fascia to arcus tendineus
    b. Posterior vaginal wall :
        i) Posterior colporrhaphy – placation of the rectovaginal fascia
        ii) Site-specific repair - perirectal fascial repair
        iii) Perineorrhaphy - approximation of pubovaginalis
        iv) Mc Call's culdoplasty – plication of uterosacrals to the vaginal vault

v) Moskowitz procedure – purse-string placation of the peritoneum in the POD

c. Vaginal approach for vaginal vault prolapse:

i) Sacrospinous colpopexy – suspension of vaginal vault to sacrospinous ligament

ii) Mc Call's culdoplasty – plication of the uterosacrals to the vaginal vault

iii) Illiococcygeus colpopexy – suspension of the vaginal vault to the illiococcygeus muscle

iv) High Uterosacral ligament suspension - vaginal vault to the uterosacral ligaments

d. Abdominal approach to vault prolapse :

i) Abdominal sacrocolpopexy - vaginal vault to the anterior sacral ligament

ii) Abdominal uterosacral suspension – vaginal vault to the uterosacral ligament

c. Laparoscopic approach :

Laparoscopic sacrocolpopexy – vaginal vault to the anterior sacral ligament

Obliterative procedures : the vagina is obliterated in women who are not sexually active and who are unfit for surgery. It is called the Neugebauer-Le Fort or Le Fort colpocleisis. Here the anterior and the posterior epithelium is removed over a large area and sutured together leaving tunnels for escape of discharge.

Prolapse surgeries are also classified as uterine sparing and uterine removal surgeries.

Uterine sparing surgeries are done for young women who desire to retain the uterus or for fertility concerns. They are as follows:

a. Fothergill/ Manchester surgery : amputation of the cervix, shortening of the cardinal ligament, anterior colporrhaphy
b. Sacrospinous hysteropexy:
c. Sling surgeries :
    i) Abdominal sacrohysteropexy – cervix suspended to sacrum with a fascial sling
    ii) Purandare's procedure - cervix suspended to the anterior abdominal wall with a fascial sling
    iii) Shirodkar's sling - cervix suspended to sacrum with tape
    iv) Khanna's sling – cervix suspended to the anterior superior iliac spine by fascia or tape

The more recent advances in the field of prolapse surgery is the use of mesh for the defects and the beginning of the era of robotic surgeries.

Quality of life :

The WHO defines health as a state of physical, mental and social well-being and not merely the absence of disease or infirmity. (84) This suggests that sound health is multidimensional. It involves patient sensed measures of health which extends from physical function, role function, social, emotional and mental state, burden of symptoms and physical well-being. As already talked about, pelvic organ prolapse has an impact on many aspects of life. It affects physical activity,social role function, emotional and mental state. And the reason for seeking medical attention itself might be not just for the prolapse but it might be due to its affect on other aspects of life. Therefore, any treatment that is undertaken for POP is not just based on restoration of anatomy but should aim on holistic improvement in the patient's quality of life. With this understanding, over the years there have been several questionnaires that have been formulated with the intention of assessing the quality of life.

Questionnaires : The assessment of pelvic floor symptoms can be done in several ways. One of the ways is by undertaking a detailed history eliciting the severity and extent of impact of symptoms on the day to day life of patients. But this method is not reproducible and not standardized. Therefore, researchers have formulated and validated standardized questionnaires for documenting the presence, severity and impact of a symptom or condition on a patient's day to day living. These questionnaires can be divided into 3 main categories :

1. Symptom questionnaires – measure the presence and severity of particular symptoms
2. Quality of life questionnaires – measure the quality of life
3. Sexual function questionnaires – measure the sexual function

Properties of a good questionnaire :For a questionnaire to be considered good it must have the following important psychometric properties :(85)

1. Validity : it implies to whether the questionnaire measures what it is intended to measure
2. Reliability : it implies to reproducibility of a questionnaire
3. Responsiveness : the ability to reliably detect the response to treatment or meaningful change

The various types of validated questionnaires that are available are broadly classified into the following categories :

1. *Symptom questionnaires* : in patients with pelvic floor dysfunction the following are available :
    a. Urinary incontinence :
        i) Incontinence severity index

ii) International consultation on incontinence questionnaire short form ICIQ-SF

iii) Urogenital distress inventory UDI

iv) Urogenital distress inventory short form UDI6

v) Kings health questionnaire

vi) Bristol female lower urinary tract symptom questionnaire BFLUTS

b. Fecal incontinence :

i) Wexner scale

ii) Fecal incontinence society index FISI

iii) Cleveland clinic fecal incontinence score

c. All pelvic floor disorders (UI, FI, POP)

i) Pelvic floor distress inventory PFDI

ii) Pelvic floor distress inventory short form PFDI-20

Out of all the above mentioned questionnaires, the one symptom questionnaire that has remained as the most valid, reliable and responsive is the PFDI for patients with POP. The short form PFDI-20 is equally valid and consists of 3 subscales. The subscales are a urinary scale, a colorectal scale and a pelvic organ prolapse scale. Each of these scales can be scored. The questions in each of these scales have scores ranging from 0-4. The grand total of all the three subscales is taken as the final score. The net score of the PFDI is a sum total of the three subscale scores

Quality of life questionnaires :

These are a group of questionnaires that is used to assess a person's total sense of well being. It includes various categories of a person's life such as, emotional health, social health and physical health. These questionnaires are of two sub categories. They are :

a. Generic health related quality of life questionnaire

b. Condition-specific quality of life questionnaire

Generic questionnaires are general questionnaires that can be used over a varied population and disease conditions. Whereas, the condition – specific questionnaires are specifically designed for particular conditions. Following are a list of quality of life questionnaires :(85,86)

1. Generic quality of life questionnaire :
    a. Full form- SF 36
    b. EuroQOL EQ-5D
2. Condition specific quality of life questionnaires:
    a. Urinary incontinence questionnaires :
        i) Incontinence impact questionnaire IIQ
        ii) Incontinence impact questionnaire short form IIQ-7
        iii) Incontinence QOL questionnaire I-QOL
        iv) Kings health questionnaire
        v) Urge incontinence impact questionnaire (urge IIQ)
    b. Fecal incontinence :
        i) Fecal incontinence QOL scale FIQL
        ii) Manchester health questionnaire
    c. Pelvic floor disorders :
        i) Pelvic floor impact questionnaire
        ii) Pelvic floor impact questionnaire short form 7 (PFIQ – 7)
3. Sexual function questionnaire :
    i) Female sexual function index FSFI
    ii) McCoy female sexuality questionnaire MFSQ

iii) Prolapse and incontinence sexual function questionnaire PISQ

iv) Prolapse and incontinence sexual function questionnaire short form PISQ-12

Out of the many condition specific questionnaires available, the PFIQ ie. Pelvic floor impact questionnaire, is one of the most valid, reliable and responsive questionnaire. This is a counterpart of the PFDI of the symptom questionnaires. The PFIQ short form 7 consists of 3 subscales : the IIQ7, colorectal and prolapse subscales. The net score of the PFIQ 7 is a sum total of the three subscale scores.

Global indices : This consists of a set of questions that are more generalized and not specific to any particular symptom or effect of an intervention.(87) This gives a generalized impression of the patient's condition in a holistic way. The advantage of this system of assessment is that it is simple, direct and easy to interpret. But the disadvantage is the lack of specificity regarding the precise reason based on which the patient makes the decision of a particular rating. Following are representations of global indices questions:

1. *VAS – visual analogue scale* : this system of psychometric analysis is widely used for several conditions. But for pelvic organ prolapse it has not been widely studied. In this system, the respondents are asked to rate a particular condition or disease severity on a scale of 0-10, with 0 being no complaint and 10 being the highest level of it.
2. *Patient global impression of improvement PGI-I* : In this system the respondent is asked to rate the improvement after treatment or intervention on a 7 point scale. Similarly, there is the Patient global impression of severity PGI-S.

Outcome measures :

Traditionally, the aim of treatment obtained for prolapse had been anatomical restoration and restoration of functional status of pelvic organs. The definition of 'cure' in patients with pelvic organ prolapse has been evolving over the years since, POP is a condition associated with a great impact on various aspects of life as physical, emotional, social, economic and mental. The various questionnaires used for psychometric analysis of patients have been used for assessing treatment outcome. However, there is no consensus regarding the best method of assessing outcome.

Various international organizations like The International Continence Society, The National Institute of Health (NIH) and World Health Organization's International Consultation on Incontinence have suggested recommendations for measuring outcome in patients with pelvic floor disorders. The basic outlines on which outcome is measured are as follows:

a. Outcome should be assessed using the same measures before and after an intervention
b. Both subjective and objective measures should be included in the assessment
c. Several domains are to be included for assessment. They are :
    i) The patient's symptoms
    ii) Quantification of symptoms
    iii) The clinician's observation—anatomical and functional
    iv) Quality of life
    v) Socioeconomic measures

A good outcome measure must be valid, reliable, easy to implement and interpret and bring out meaningful information. There has been no established gold standard for measuring outcome in pelvic floor disorder patients. Over the past decade there have been several studies that looked at patient-based outcomes such as quality of life, symptom questionnaires as methods for measuring outcome rather than only anatomical and functional restoration of pelvic organs. A survey done in 2002 by Tincello et al among patients, Medical practitioners and nurses found that improvement in quality of life and subjective measures were the two most popularly used outcome measures in urogynecology.(5)

Patient-selected goals is a relatively new method for measuring outcome that has been widely studied in the past decade. This has been based on the decision of The Institute of Medicine, Washington DC in 2001 that treatment in the field of medicine needs to be more patient-centered. In the 2001 workshop on standardization of terminologies for pelvic floor disorders, the definition for “cure” after surgery was assigned to “optimal anatomic outcome”. The “optimal anatomic outcome” in prolapse patients was considered as stage 0 and the “satisfactory anatomic outcome“ was considered as pelvic organ support leading to prolapse at least 1 cm above the level of the hymen.

Since then there have been several studies challenging that definition of “cure” for pelvic floor disorder patients.

In 2002, a study was done by Hullfish et al which looked at patient selected goal achievement after surgery at 6 weeks and 3 months. It was reported that

these patient selected goals ranged between symptom resolution, activity related, social role, sexual life or self image. They concluded that patient selected goals are quick and easy to assess. This outcome measure helps physicians to care for their patients better. (88)

In 2003, a study done by Shott et al, assessed the correlation between subjective achievement of patient selected goals, overall patient satisfaction and objective outcome measurement. The overall patient satisfaction was assessed by using two global indices such as, Patient Global Impression of Severity (PGI-S) and Patient Global Impression of Improvement (PGI-I). Objective outcome measurements used were demonstrable urodynamic stress urinary incontinence and post operative stage 0 or 1 prolapse. Post operative follow up was done at 6 weeks and 3 months. They reported that patient satisfaction was moderately correlated to goal achievement. But objective cure was not correlated to satisfaction. They concluded that both objective and subjective outcome measures are needed to assess patient satisfaction. Clinicians cannot predict the individual patient's goal. But these patient reported goals seems to be the primary reason for them undergoing surgery. (13)

In 2004, Hullfish et al did a continuation of the study published in 2002. They now looked at long-term goal achievement. The mean duration of follow up was 1.8 years, range from 1-3 years. They reported that 72% of goals were achieved at short term period and 68% were achieved at long term follow up. The results of long term goal achievement correlated with the quality of life scores on the IIQ-7 and the UDI-6. This suggests that goal attainment scale measurement of surgical outcome is a valid method of assessing surgical

success in pelvic reconstructive surgeries. This system of outcome measurement can complement the existing clinical and quality of life instruments for understanding surgical success. (9)

A study published in 2007 by Lowenstein et al, reported that patient selected goals as the fourth dimension of assessment in pelvic floor disorders. The other three dimensions being, patient's symptoms, physical findings and quality of life assessments. In the study, patients were further asked to prioritize their goals. The study reported that the primary goal acted as a determinant for their choice of treatment modality, surgical or medical. They also reported that the primary goal correlated significantly with higher scores in the subscales of the PFDI questionnaire. (14)

S. Srikrishna et al in 2008 looked at the quantitative establishment of patient's expectations and goals for surgery and the qualitative measurement of affect on quality of life. They used a semi-structured interview based approach for the qualitative data collection. The authors of the study reported that although, the disease specific quality of life questionnaires gives a broad understanding of patient bother. It is the understanding of the patient's goals and expectations of the surgery that will further help the clinician in individualizing treatment care and improving outcome. (7)

In 2009, Hullfish published another study, assessing the relationship of patient selected goals and disease specific quality of life questionnaires. The study reported that patient selected goal achievement was significantly associated with improvement in quality of life scores and patient satisfaction. (11)

In 2009, a study was done in an attempt to define success after surgery for pelvic organ prolapse. They analyzed various definitions for surgical success in terms of anatomy, patient perception of improvement and treatment satisfaction and improvement in disease specific quality of life questionnaires. They reported that treatment success varied depending on the definition used, 19.2% - 97.2%. While following the definition of cure as given by the 2001 NIH workshop, “the optimal anatomic outcome”, surgical success was for only 19.2% to 57.2%. but when success was defined as “subjective cure” ie. Absence of bulge, success rates were higher (92.1%). Subjective cure was significantly associated with patient’s assessment of treatment success and improvement. Therefore, the study concluded that anatomic cure alone cannot be taken as the definition of success following surgery for pelvic floor disorders. (70)

In 2011 a study done by Lawndy was published which looked at patient’s expectations in terms of their hopes and fears related to pelvic floor reconstructive surgery. This was the first study that assessed patient’s fears, apart from goals related to the surgery. Patient’s expectations can sometimes be unrealistic and unrelated to the pelvic floor disorder. Awareness of these expectations can help in appropriate patient counseling prior to surgery. Fears of patient’s undergoing surgery is another very sensitive issue. Not many clinicians make note of this. But these fears do play a significant part in patient’s overall improvement and decision making. The study reported that women who undergo surgery for pelvic floor disorders, have a wide range of hopes and fears. They need to be addressed by appropriate counseling prior to surgery in order to improve patient satisfaction. (6)

Our study “hopes and fears in patients undergoing surgery for pelvic organ prolapse” is probably the first of its kind to be done in Indian society. All the above quoted studies have been done in western populations. The questionnaires that have been popularly used and validated for pelvic floor disorders have been validated for use in western countries.

Indian perspective of pelvic floor disorders :

In our state of Tamil Nadu alone there are 3.59 crores of women according to the 2011 population statistics. (89) The literacy rates among women in urban India is 80% and only 59% among women in rural India.(89) The number of languages spoken in India as per the 2001 census is 29. In India according to the 2010 statistics 29.8% of the population are still below poverty line.(90)

For our Indian community, the relevance, the reliability and the ease of use of these disease specific quality of life questionnaires has not been validated. Many different languages are spoken in any given community set up. There are 29 languages spoken all over India as per the 2001 census. (91) The unequal mix up of socioeconomic status groups in Indian communities. The literacy rates in India being only 59% in rural communities.(89)These variations make uniform assessment with a questionnaire validated in English a difficult task.

Our hospital, Christian Medical College, Vellore, is a tertiary care centre catering to patients from all over India. There are around 200 patients attending Gynaecology OPD in a month with approximately 100 major gynecological surgeries performed in a month. Of these approximately 10 surgeries a month are related to Urogynaecological problems.

These studies have led us to consider as to which outcome measure may be the most feasible and appropriate for our community in order to assses the success of treatment. Studies done earlier (14) have shown that patient selected goals and their perception of the primary goal is the driving force for treatment decision. Our community has also been influenced by the changing trends of the 20th century. The role of women in society and family are influenced by these changes. Do our women need a different outcome measure for pelvic floor reconstructive surgery. Are their expectations met in undergoing the treatment offered? Which is a better outcome measure in our community?

This study attempts to understand these queries from the patients perspective.

Methodology :

The study commenced after obtaining approval from the Institutional Review Board.

Study design : Prospective observational study

Setting: Women with symptomatic pelvic organ prolapse admitted for surgery in the department of Obstetrics and Gynecology in our institution, Christian Medical College and Hospital were approached for the study.

Inclusion criteria :

1. Women planned for pelvic organ prolapse surgery who are≥ 18 years of age

Exclusion criteria :

1. Patients with symptomatic pelvic organ prolapse admitted for pelvic reconstructive surgery not willing to participate in the study
2. Patients who are unable to understand the interview questions and express their hopes and fears due to language barrier.

Hypothesis:

Symptom relief has been reported as the primary concern for patients seeking treatment for POP. The sample size for the study was based on the hypothesis that "50% of patients with pelvic organ prolapse will be highly satisfied with regards to symptom relief following corrective surgery in our hospital".

Sample size : Using the above mentioned hypothesis, the sample size was calculated with the following formula:

- Formula: $n = \frac{Za^2 pq}{d^2}$

- where, d – precision 10% Z : 50% a = 1.96 q = 100 - p
- Using this formula we obtained a sample size of 100.

Informed consent

A written informed consent was obtained in the patient's own language prior to their recruitment for the study. They were provided with an information sheet that summarized the details of the study and its purpose. No financial or materialistic benefits were offered to the participants of the study. A copy of the patient information sheet and the informed consent are attached as appendix.

Methodology :

The study commenced preoperatively when patients were admitted for surgery in the ward. They were subjected to an in depth, semi-structured interview. The questions were directed to collect information regarding their demographics, socio economic status and reason for seeking treatment. The interview consisted of open ended questions pertaining to seeking information for patient bother due to the prolapse per say, urinary problems, fecal problems, problems in day to day activities, social activities and sexual life, if any. Patients were asked to quantify the magnitude of the affect on their quality of life under each of these categories of complaints on a visual analogue scale (VAS) of 0-100. Where 0 meant no bother and 100 meant very severely affected.

They were also asked to quantify the perception of their quality of life with the current condition of pelvic floor dysfunction on a VAS scale of 0-100.

The patients were then asked to prioritize the problems enlisted by them, during the semi structured interview, from 1-5. With the 1st being the most troublesome and their primary concern for seeking treatment.

They were then asked to enlist a maximum of 5 hopes (goals) and fears as perceived by them, in their own language, with respect to the pelvic reconstructive surgery that they were admitted for.

The POPDI 20 and the PFIQ 7 questionnaires were then administered.

They were then subject to examination as per the protocol that was followed by the Department for all patients undergoing surgery for pelvic organ prolapse.

A subset of patients were followed up post operatively at 6 weeks and 3 months either in person or telephonically as per their convenience.

During the post operative follow up, they were reminded of their previously enlisted hopes and fears and their self reported problems pertaining to their then condition of pelvic floor dysfunction. They were then asked to quantify their perception of the fulfillment of their hopes and the resolution of their fears over a visual analogue scale of 0-100. Here 0 being not achieved or not resolved and 100 being fully achieved or resolved. They were also asked to quantify their present quality of life with respect to their preoperatively enlisted problems on the visual analogue scale of 0-100.

They were then asked to describe their perception of the ‘worst aspect’ and the ‘best aspect’ of the surgery. They were also asked to quantify their perception of satisfaction with regards to the surgery, on a scale of 0-100. And for those patients who were not 100% satisfied with the surgery, they were asked to describe the reasons for their dissatisfaction.

They were also asked global questions pertaining to their perception of the severity of their condition prior to surgery and their present condition of improvement post operatively.

The two questionnaires POPDI 20 and PFIQ 7 were then administered.

Statistical analysis :

For analytical purpose the responses obtained from the interview regarding their "hopes and fears", their self reported problems pertaining to their pelvic floor dysfunction and their prioritized list of problems, were classified into several domains based on other similar studies(6,14). The domains are as follows :

1. related to symptom resolution
2. related to increasing activity
3. related to emotions
4. related to social relationships and self image
5. related to sexual life
6. Others (that did not fit into one of the other categories and those that fit into two or more categories)

The top three priorities that were enlisted by each of the patients were also categorized into similar domains and analyzed.

Analysis : A quantitative and qualitative analysis was done with the responses obtained.

a) Descriptive statistics were reported using mean ± SD for continuous variables N(%) for categorical variables
b) Chi square / Fischer's exact tests were done to find association between the post operative POPDI20 and PFIQ7 scores with the achievement of hopes and resolution of fears.
c) To look at the association between the scores of the study instrument and the validated condition specific questionnaires POPDI 20 and PFIQ7 scale and their subscales, the Pearson's Rho correlation coefficient was used.

d) Regression analysis and actual predictive equation was used to calculate the correlation between the scores of the study instrument and the validated condition specific questionnaires POPDI20 and PFIQ7 scale and their subscales

Results :

100 patients were approached for the study. Of them 2 were excluded since one patient refused and the other patient's surgery was cancelled as she had a co existing medical problem that needed further evaluation.

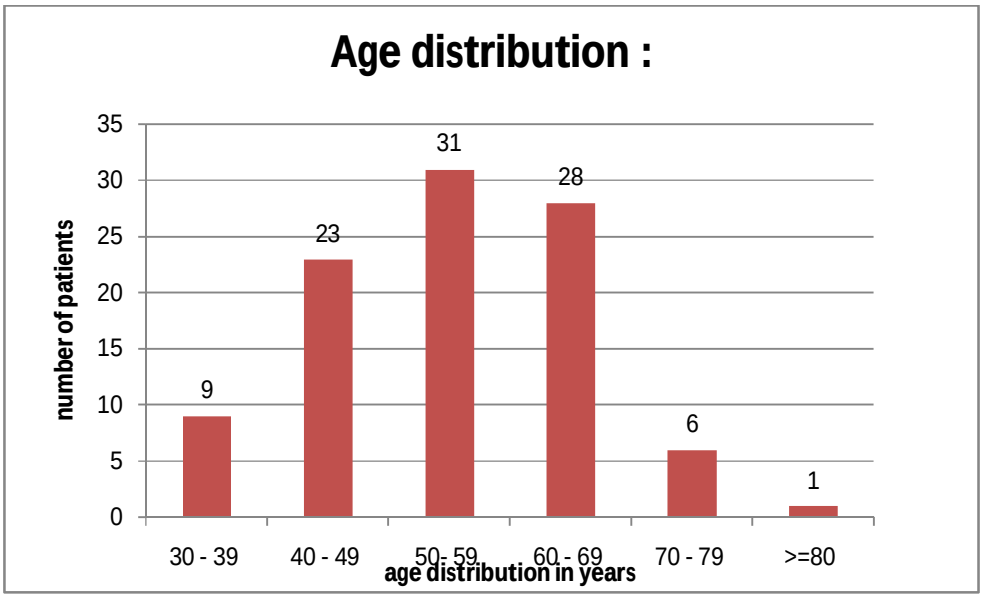
The remaining 98 patients were included in the study. Therefore, out of the 98 study patients**,** 71 patients had the 1st follow up done at 6 weeks 60 patients followed up at 3 months and 58 patients were followed up at both 6 weeks and 3 months.

A) Demographic details :

Age in years ---- median (range)	54 (33 - 85)
SES class distribution ----- number (percentage)	
SES class 1	28 (28.57%)
SES class II	57 (58.16%)
SES class III	10 (10.2%)
SES class IV	3 (3.06%)
Primary language spoken ….. number (percentage)	
Tamil	67 (68.36%)
Hindi	16 (16.3%)
Bengali	15 (15.3%)

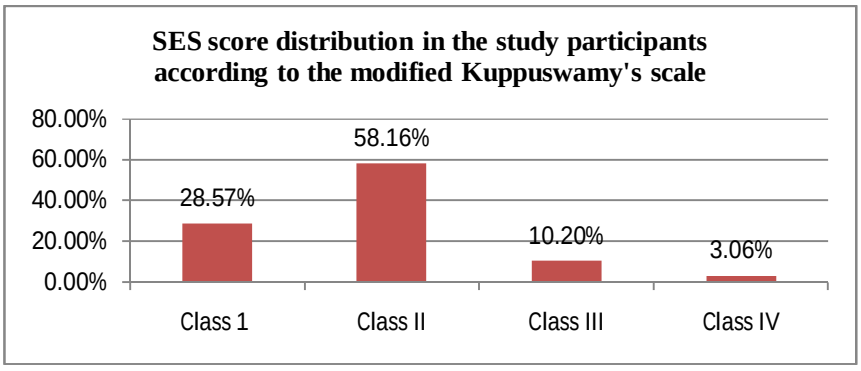
Table 1 : showing the demographic details of study patients

The ages of patients in the study group were normally distributed as shown in the graph below :



Graph 1 : showing the age distribution among study patients:

Maximum of our study patients belonged to class 11 with least number of patients in class IV. The SES distribution of patients according to the modified Kuppuswamy's classification is as follows:



Graph 2 : showin the distribution of study participants according to the various SES classes by the modified Kuppuswamy's scale

Occupation of patients : Of the 98 patients 68 of them were housewives, 25 were laborers (9) semi skilled workers and 16 farmers, 4 professional, and 1 hostel warden and 3 professionals.

Marital status : of the 98 patients 21 were either widowed or separated from husband. 77 were married.

The distribution of patients according to the primary languages spoken by them is given in the table above. Some of the study participants knew more than one language. The other languages known by some of them were Telugu and English.

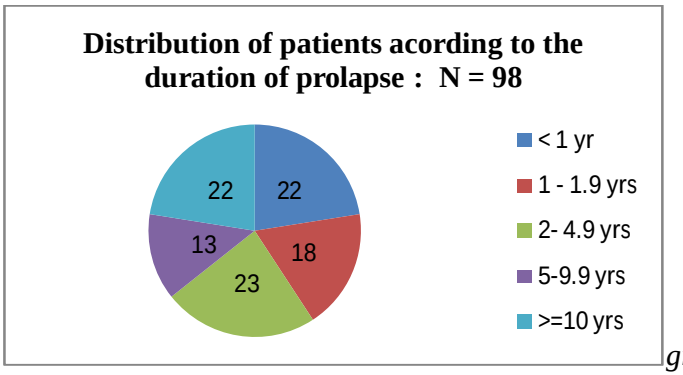
Details in relation to pelvic floor dysfunction :

Parity ------- median (range)	3 (0 - 9)
Menopausal women ------- number (percentage)	71 (72.44%)
Duration of menopause in years ----- median (range)	10 (1 - 30)
Duration of prolapse in years ----- median (range) < mean >	2 (2 months – 30) <5.1>
Stage of prolapse ----- number (percentage)	
Stage 1 *	1 (1.02%)
Stage 2	7 (7.14%)
Stage 3	65 (66.32%)
Stage 4	25 (25.51%)

table 2 : showing the distribution of POP related demographics of study patients:

** with incarcerated vaginal ring pessary who had stage 3 POP prior to its incertation*

Duration of prolapse: This ranged from 2 months to 30 years, with a mean of 5.1 years and a median of 2 years. The maximum number of patients (63) had a duration of less than 5 years (64.28 %). The distribution of patients according to the duration of prolapse is as follows :



graph 3: showing the distribution of patients according to the duration of prolapse:

*Stage of prolapse:*Most of our study patients belonged to stages 3 and 4 of prolapse as this study was done among patients needing surgical repair.

B) Primary objective 1 : To enlist the hopes and fears of our patients undergoing surgery for pelvic organ prolapse in their own words:

Hopes and fears:

The total number of hopes responses for the 98 patients was 207. This ranged from 1-4 with a mean and median of 2.Out of these 207 responses for hopes, majority of them belonged to domain 1 ie. symptom relief (139 ; 67.14 %). The second most common was domain 2 ie. Related to activity (40 ; 19.32 %). There were no hopes under domains 3 and 4 ie. related to emotions and social life. There was only one hope under domain 5 ie. related to sexual activity (1 ; 0.4 %). There were a total of 27 hopes (27 ; 13.04 %) that belonged to domain 6 i.e. others, since they could not be classified into any of the 1-5 domains or belonged to more than one domain.

The total number of responses for fears was 79, for the 98 patients which ranged from 0-4 with a mean of 0.8 and a median of 1. The majority of fears (64; 81 %) belonged to domain 6 ie. others because either they could not be classified into any of the 1-5 domains or belonged to more than 1 domain. There were only 15 fears (15; 18.98 %) under domain 1 ie. related to

symptoms. There were no fears under the domains 2,3,4 and 5 ie. domains related to activity, emotions, social life and sexual activity.

Domains :	Total number of response for preoperative fears : N= 79	Total number of responses for preoperative hopes : N= 207
(Domain 1) symtom related	15 (18.98 %)	139 (67.14 %)
(Domain 2)activity related	0	40 (19.32 %)
Domain 3 – related to emotions	0	0
Domain 4 – related to social life	0	0
Domain 5 – related to sexual life	0	1 (0.4 %)
Domain 6 – others	64 (81 %)	27 (13.04 %)

Table 3 : showing the domain wise distribution of responses for pre operative hopes and fears:

Following are enlisted a sample of the responses for pre operative hopes and fears question, as described by patients according to the various domains.

Preoperative Hopes:

Domain 1 : related to symptom resolution:

a) " my urinary problems will go away"
b) " my problems while passing motions will settle"
c) pain in the lower abdomen will settle"
d) " the pressure in my lower abdomen will settle"
e) " backache will settle"
f) " the dragging sensation in my vagina will get better"
g) " my joint pains will decrease"
h) "my hernia will get corrected"
i) "I can now eat and have no mass coming out from below after eating"

Domain 2 : related to increasing activity: a) " will be able to get back to my work" b) " difficulty in walking will settle" c) " difficulty in sitting will settle" d) "be able to do day to day activities without having any problems"
Domain 5 : related to sexual activity a) " pain during intercourse will settle"
Domain 6 : others a) "will be normal again to take care of my family " b) "my uterus will be removed" c) "will be able to live longer to take care of my family" d) "have a normal life again"

Table 4 : A sample of the pre operative hopes of patients as described by them according to the various domains

There were no responses for hopes under domains related to emotion and social life.

Pre operative fears :

Domain 1 : related to symptom resolution: a) "of pain" b) "will I have urinary problems after surgery" c) " will my lower abdominal pain and body aches settle after surgery"
Domain 6 : others a) " will I improve and be normal again after surgery?" b) " will I withstand the surgery" c) "of complications" d) "of infection" e) "of anesthesia" f) " unaware of what the surgery is like"

Table 4 :Distribution of responses for pre operative fears of patients according to the various domains

Distribution of responses for pre operative hopes and fears according to the various domains among patients with various stages of prolapse, duration of prolapse, SES classes and age of patients:

Pre- operative Hopes :

	Domain 1 Symptom related	Domain 2 Activity related	Domain 3 emotional	Domain 4 Social life related	Domain 5 Sexual life related	Domain 6 others
Age distribution of patients in years:						
a) 30-39	11	8	0	0	0	2
b) 40–49	33	9	0	0	1	11
c) 50-59	51	10	0	0	0	5
d) 60-69	34	12	0	0	0	8
e) 70-79	9	1	0	0	0	1
f) >=80	1	0	0	0	0	0
SES classes of patients:						
a) Class I	39	4	0	0	0	10
b) Class II	85	20	0	0	1	14
c) Class III	11	12	0	0	0	3
d) Class IV	4	4	0	0	0	0
According to the duration of						

prolapse:in yrs						
a) <1	30	10	0	0	0	5
b) 1-1.9	26	4	0	0	1	4
c) 2-4.9	33	7	0	0	0	6
d) 5-9.9	18	3	0	0	0	5
e) >=10	33	15	0	0	0	7
According to the stage of prolapse:						
a) Stage 1*	1	0	0	0	0	0
b) Stage 2	11	1	0	0	1	2
c) Stage 3	90	25	0	0	0	19
d) Stage 4	38	14	0	0	0	7

Table 5: distribution of pre operative hopes of patients according to their age distribution, SES classes, duration and stage of prolapse in the various domains:

As depicted in the table above there is no difference in the pattern of the distribution of preoperative hopes among the various domains. Irrespective of the age of patients, their SES class, duration and stage of prolapse, all have the domain 1 (symptom resolution) as the foremost hope followed by the others. Patients did not describe hopes under domains 3 and 4 ie related to social life and emotions.

Pre operative Fears:

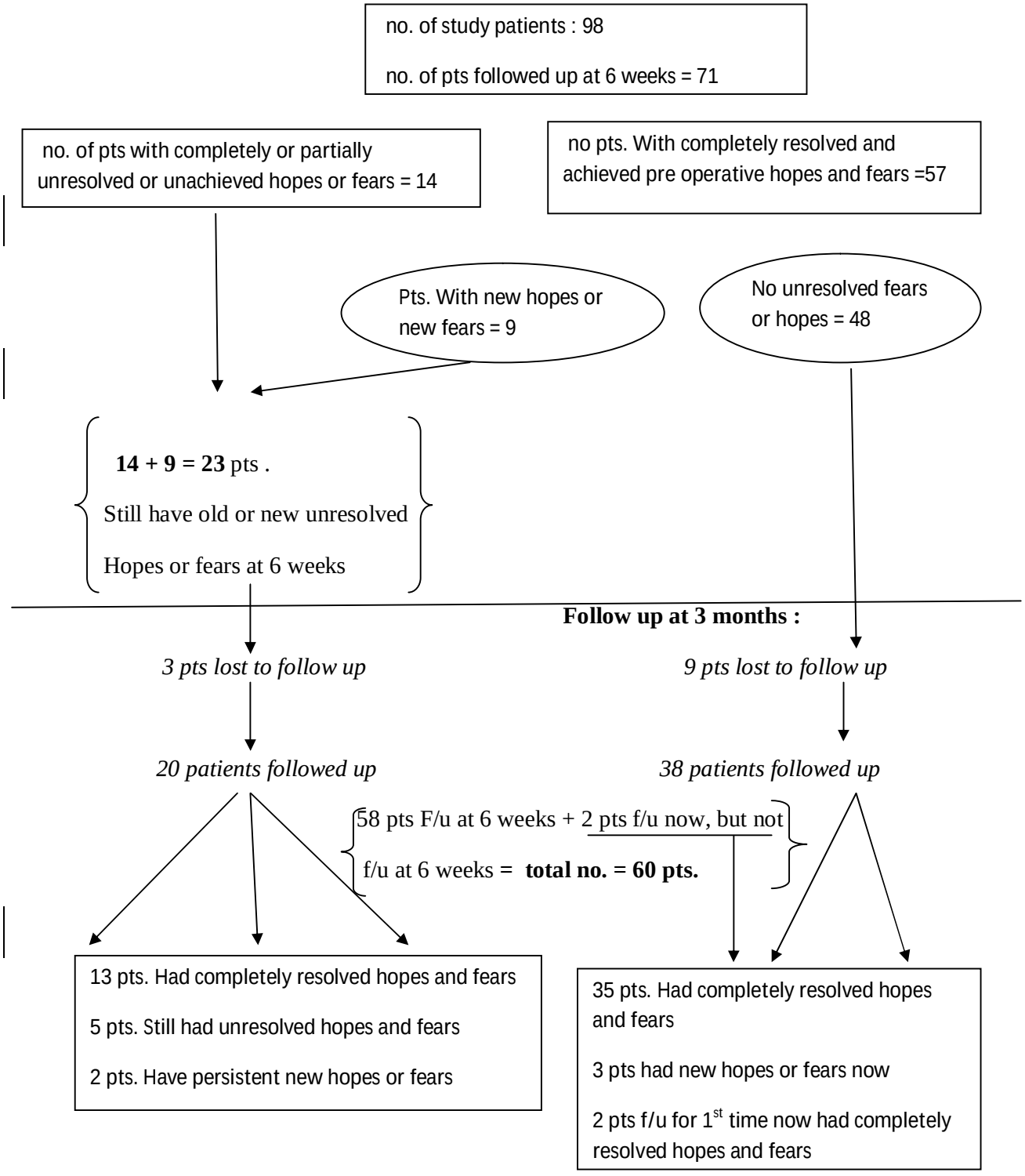
	Domain 1 Symptom related	Domain 2 Activity related	Domain 3 emotional	Domain 4 Social life related	Domain 5 Sexual life related	Domain 6 others
Age distribution of patients in years:						
g) 30-39	0	0	0	0	0	8
h) 40–49	6	0	0	0	0	19
i) 50-59	4	0	0	0	0	19
j) 60-69	4	0	0	0	0	16
k) 70-79	1	0	0	0	0	1
l) >=80	0	0	0	0	0	1
SES classes of patients:						
e) Class I	3	0	0	0	0	14
f) Class II	10	0	0	0	0	39
g) Class III	1	0	0	0	0	7
h) Class IV	1	0	0	0	0	4
According to the duration of prolapse:in yrs						
f) <1	4	0	0	0	0	13
g) 1-1.9	8	0	0	0	0	10
h) 2-4.9	0	0	0	0	0	11

i) 5-9.9	0	0	0	0	0	14
j) >=10	2	0	0	0	0	16
According to the stage of prolapse:						
e) Stage 1*	0	0	0	0	0	1
f) Stage 2	2	0	0	0	0	3
g) Stage 3	9	0	0	0	0	34
h) Stage 4	4	0	0	0	0	27

Table 6 : showing the distribution of pre operative fears in the various domains among patients in the various age groups, SES classes, duration and stage of prolapse:

As depicted in the table above the preoperative fears belonged to only domains 1 and 6 (symptom resolution and others). There were no pre operative fears in the other domains 3, 4 and 5. This pattern was similar among the various age groups, SES classes, duration and stage of prolapse of patients.

C) Secondary objective 1 : **To measure the achievement of hopes and resolution of fears in a subset of patients willing for follow up post operatively either telephonically or in person, at 6 weeks and 3 months**



Therefore at the end of 3 months 58/98 (59.18%) had both 1st and 2nd post operative follow up.

Of the 58 patients :

a) 13 + 35 = 48 patients had completely resolved hopes and fears at end of 3 months (48/58 ie 82.7%)
b) 5 patients still had unresolved fears or unachieved hopes at end of 3 months (5/58 ie. 8.6%)
c) 2 + 3 = 5 patients had new hopes or fears at end of 3 months (5/58 ie. 8.62%)

A sample of the descriptions of the unachieved or partially achieved hopes and unresolved or partially achieved fears with some related comments are as follows :

Unachieved or partially achieved hopes:	**Specific related comments:**
1st post operative follow up at 6 weeks: a) "backache resolved only 50%" b) "difficulty in sitting" better only by 50% because of pain in suture site c) "be back to work again" this ranged from 0-50% of achievement among patients d) "to be normal again" had only 50% achievement e) "joint pain"reduced only be 50% *2nd post operative follow up:* a)"pain and difficulty during sitting and walking" resolved from 80 – 90%	*1st post operative follow up at 6 weeks:* - "not good"because having pain in the suture site - "not well" because of pain in buttock and pain while passing motions - Having persistent joint pain *2nd post operative follow up :* - "much worse than before"because of

b) "urinary problems resolved only by 90%" c) "mass descending per vaginum settle only by 50%"	persistent pain in suture site - "unhappy" because having a persistent mass in vagina while passing motions
Unresolved or partially resolved fears : *1st post operative follow up :* a) "worsening of lower abdomen pain and body aches" resolved only by 50% b) "worsening of problems after surgery" resolved by 50 – 75% among patients *2nd post operative follow up :* a) "fear of recurrence" resolved from 10 - 90% b) "fear of complications" resolved only by 10%	**Related comments:** *1st post operative follow up:* - Pain in buttock and rectal region presentpost operatively - "having urinary leakage on coughing now" after surgery which was abscent pre operatively *2nd post operative follow up:* - Having urinary problems now - Having mass in vagina and pain on passing motions

Table 7: showing a sample of the unresolved and unachieved fears and hopes respectively and some of the comments of patients during the 1st and 2nd post operative follow ups

New hopes and fears during the post operative follow up at 6 weeks and 3 months:

1st post operative follow up at 6 weeks :

During the 1st follow up at 6 weeks, 23 patients had some problem. There were 33 responses for new hopes. Of these 7 responses were related to urinary problems (7 / 33 ; 21.21 %). There were 6 patients who had new fears. There were 7 responses for new fears. The new hopes belonged to activity related and symptom related domains only. New fears belonged only to activity related and domain for others. Following are the list of new hopes and fears according to the domains, at the 1st post operative follow up at 6 weeks.

New hopes :

Domain 1: related to symptom relief: **New hopes :** a) "my backache will get better" b) "my lower abdomen pain will settle" c) "the heaviness that I have in my lower abdomen will settle" d) "my pain in the suture site will improve" e) "my pain in the buttock region will settle" f) "my urinary problems will settle" g)"my pain in the region of passing motions will settle" g) "the feeling of dryness in my vagina will settle" h) "the burning sensation in my upper abdomen will settle"
Domain 2 : related to activity : **New Hopes :** "the difficulty that I have during walking and sitting will improve"

Table 8 Sample of new hopes as described by patients during the 1st post operative follow up at 6 weeks

New Fears :

Domain 2 : related to activity : **New Fears :**

a)“ will I be able to work like before again ie. carry weights?”
Domain 6 : others : **New Fears:** a) “will my problems normalize ?” b) “ will I get better ?” c) “ will I be normal again ?” d) “will my problems worsen ?” e) “of infection ?”

Table 9 Sample of new fears as described by patients in the 1st post operative follow up at 6 weeks

During the 2nd post operative follow up :60 patients out of the 98 recruited patients could be followed up at 3 months. 2 of those who were followed up at 3 months could not be followed up at 6 weeks.

Of these 60 patients who were followed up at 3 months, there were 15 responses for new hopes and 6 responses for new fears.

New hopes :

The 15 responses for new hopes belonged to domains 1 and 2 ie related to symptom resolution and increasing activity. There were no new hopes mentioned in the other domains. Following is a sample of the described new hopes by patients :

Domain 1 : related to symptom resolution: **New hopes :** a) “I again have the feeling of a mass descending below since the past 20 days. I hope this will settle” b) “my pain in the lower abdomen will settle” c) “the burning sensation that I have while passing urine will settle” d) “pain in the suture site will settle” e) “the heaviness that I have in my lower abdomen will settle” f) “my backache will settle” g) “my joint pain and backache will go away” h) “the swelling in my vagina seen during passing motions will go away” i) “the pain that I have during passing motions will settle”

Domain 2 : related to activity:
New hopes : a) "I hope that the difficulty that I have during sitting and walking will reduce"

Table 10 showing a sample of the new hopes as described by patients at 3 months follow up

New fears :

The 5 patients of the 60 followed up, had 6 new fears. All the 6 new fears belonged to domain 6 ie others category. The new fears as described by the 5 patients are as follows:

Domain 6 : others
New fears: a) "will I worsen" b) "will I have recurrence of problems" c) "will I ever get better ?"

Table 11:showing a sample of the new fears of patients at 3months follow up

D) Primary objective 2 :To assess quality of life using validated POP questionnaires POPDI-20 and PFIQ-7.

The validated questionnaires POPDI 20 and PFIQ7 were administered to all the 98 of the study patients preoperatively and to all the patients who were followed up post operatively. The scores obtained pre operatively were as follows:

Scale and subscales N = 98	Minimum score	Maximum score	Mean score	Median score	SD deviation
POPDI 6 subscale	0	79.16	27.26061	25	17.26498
CRADI 8 subscale	0	40.62	4.394898	0	9.14072
UDI 6 subscale	0	91.66	25.73153	25	22.1722
POPDI 20 total	8.33	183.33	57.47357	51.035	39.42815

scale*					

*Maximum permissible score for scale is 300 and for each subscale is 100

Table 12; showing the pre operative scores for POPDI 20 and PFIQ7 along with the scores for their subcales;

The POPDI 20 scale is a sum of three subsclaes (POPDI6, CRADI8 and UDI6). The preoperative scores obtained in our study patients is depicted in the table above. The median score for CRADI 8 was 0 since many patients had 0 score for it. The UDI 6 and the POPDI 6 had a median score of 25 therefore the cumulative score POPDI 20 is mainly contributed by POPDI 6 and UDI 6 scores in our patients.

Scale and subscales N=98	Minimum score	Maximum score	Mean score	Median score	SD deviation
PFIQ bladder subscale	0	95.14	13.34102	0	22.12679
PFIQ bowel subscale	0	47.57	1.569286	0	7.07785
PFIQ vagina subscale	0	99.9	26.86061	14.27	30.90139
PFIQ 7 total scale*	0	233.09	41.46429	23.78	50.83675

*permissible score is for scale is 300 and each subscale is 100

T*able 13: this shows the preoperative scores for the PFIQ7 and its subscales PFIQ for bladder, bowel and vagina*

The above table showing the preoperative scores for the PFIQ7 questionnaire and its subscales suggests that the PFIQ7 cumulative score is mainly dependant on the PFIQ

subscale score for vaginal symptoms in our study patients. The median score for the PFIQ subscales for bowel and bladder is 0 suggesting that many of our study patients had 0 score for these subscales.

E) Secondary objective 2 :To compare patient's perception of achievement of hopes and the resolution of fears with the results obtained for the validated questionnaire on quality of life.

There were 71 patients followed up at 6 weeks (post op 1). Of these 71 patients 57 had completely resolved fears and completely achieved hopes. The remaining 14 patients had partially resolved or partially achieved or unresolved hopes and fears. The post op POPDI 20 and PFIQ 7 scores for these two groups of patients were compared to look for a correlation. Following 2x2 tables shows the diagramatic representation of the same:

	Post op 1 with completely resolved fears and completely achieved hopes	Post op 1 with partially resolved or unresolved fears and partially achieved hopes or unresolved hopes	
POPDI 20 scores of 0 (completely resolved fears and hopes)	51	8	59
POPDI 20 scores of >0 (partially resolved or unresolved hopes and fears)	6	6	12
	57	14	71

Table 14 : this shows cross tabs between those who have completely achieved or resolved hopes and fears with those who have partially resolved or unresolved hopes and fears vs the post op POPDI 20 score those with scores of 0 and those with any score >0.

The above 2 x 2 table shows that of the 57 patients who had post op POPDI 20 scores of 0, 51 patients (86.4%) had completely achieved or resolved hopes and fears and 8 patients (13.6%) had partially resolved or achieved or unresolved or unachieved hopes and fears.

And out of the 12 patients who had post op1 POPDI 20 scores of more than 0, 6 patients had (50%) completely achieved or resolved hopes and fears and 8 patients (50%) had partially resolved or achieved or unresolved or unachieved hopes and fears.

The p value by Fischer's exact test is <0.01 for the above 2x2 table. This shows significant correlation between the two groups (patients with completely achieved hopes or completely resolved fears and those with partially resolved or unresolved hopes and fears with those patients who have post op POPDI 20 scores of 0 and > 0)

	Popst op 1 with completely resolved fears and completely achieved hopes	Post op 1 with partially resolved or unresolved fears and partially achieved hopes or unresolved hopes	
1 PFIQ 7 scores of 0 Completely achieved or resolved	52	5	57
PFIQ 7 scores of >0 Partially resolved or unresolved	5	9	14
	57	14	71

Table 15 :this shows crosstabs between those who have completely achieved or resolved hopes and fears with those who have partially resolved or unresolved hopes and fears vs the post op PFIQ7 score those with scores of 0 and those with any score >0.

The above 2 x 2 table shows that of the 57 patients who had post op PFIQ 7 scores of 0, 52 patients (91.2%) had completely achieved or resolved hopes and fears and 5 patients (8.8%) had partially resolved or achieved or unresolved or unachieved hopes and fears.

And out of the 12 patients who had post op1 PFIQ 7 scores of more than 0, 5 patients had (35.7%) completely achieved or resolved hopes and fears and 9 patients (64.3%) had partially resolved or achieved or unresolved or unachieved hopes and fears.

The p value by Fischer's exact test is <0.01 for the above 2x2 table. This shows significant correlation between the two groups (patients with completely achieved hopes or completely resolved fears and those with partially resolved or unresolved hopes and fears with those patients who have post op POPDI 20 scores of 0 and > 0)

F) Secondary objective 3 : To look at the merits of our the study instrument compared to that of a standardized questionnaire

The study instrument :

Scores on a VAS scale of 0-100 were obtained for various categories concerning which the patient specified a symptom bother. Therefore out of the 98 patients :

97 / 98 ----(98.97%) ---- were affected by the mass

69/98 ---- (70.4%) ----- were affected by urinary problems

20/98 ----- (20.4%) ----- were affected by fecal problems

76/98 ---- (77.55%) ----- were affected in their daily activity

15/98 ----- (15.3%) ----- were affected in their social life

16 ---- out of 40 who were sexually active ---- 0.4 % ---- were affected in their sexual life due to the prolapse.

The scores obtained over a VAS scale of 0-100 for various categories of patient bother such as related to mass per say, urinary problems, fecal problems, related to activity, related to social life and related to sexual activity are as follows:

Categories of patient bother	Minimum * score given by study participants	Maximum * score given by study participants	Mean score	Median score	SD standard deviation
related to mass N : 97#	20	100	68.96907	70	16.456
related to urinary problems N : 69#	30	100	75.57971	80	15.986
related to fecal problems N : 20#	20	90	55.25	50	19.295
related to activity N: 76#	20	100	70.32895	80	19.989
related to social life N : 15#	50	100	69.66667	75	17.975
related to sexual life N : 16#	20	100	56.5625	50	19.211
Over all score N =	30	100	74.9359	80	15.703

98#					

*this is the maximum and minimum scores mentioned by patients. The maximum and minimum permissible scores are 100 and 0 respectively

this specifies the number of patients who had a problem in that respective category

Table 16 : showing the pre operative scores obtained in the various categories of patient bother using the study instrument

Description of responses under the various categories of patient bother :

There were a total of 520 responses for patient bother given by the 98 study patients in the semi structured interview.

Of these 520 responses, 152 (29.23 %) were related to mass, 154 (29.61 %) were related to urinary problems, 26 (%) were related to fecal problems, 148 (28.46 %) were related to activity bother, 23 (4.42 %) were related to social and emotional bother and 17 (3.26 %) responses were related to sexual life.

Of the many responses the most frequently mentioned patient bother was “increase in size of mass in vagina” (101 responses ; 19.42 %) . The second most common was “difficulty in sitting or walking or bending over” (97 responses ; 18.65 %). The third most common was “feeling of incomplete voiding” (36 responses ; 6.92 %). The next common were “feeling of urgency to void” and “difficulty in doing day to day activities”, each of which were 22 responses (4.23 %)

Patient bother due to prolapse mass :97 out of the 98 patient had complaints due to the mass per say. The main concern for most of the patients was, the progressive increase in size of the mass descending into the vagina. Some were troubled by the associated vaginal discharge. A sample of the responses given are:

“I find it difficult to walk because of the mass rubbing against my legs”

"it feels disgusting to look at the mass"

Table 17 : sample of the various descriptions of bother due to the mass as stated by patients

Description of patient bother due to mass	Number and proportion of such responses N=152
Increase in size of mass in the vagina	101 (66.44 %)
Vaginal discharge, foul smelling or blood stained	16 (10.52 %)
Difficulty in sitting and walking due to mass rubbing against legs	12 (7.89 %)
Lower abdomen pain and discomfort	8 (5.26 %)
Low backache	10 (6.57 %)
Mass felt in the vagina	1 (0.66 %)
Vaginal discomfort and pain	2 (1.31 %)
Dragging sensation in the vagina	1 (0.66 %)
Feels disgusting looking at the mass	1 (0.66 %)

Table 18:shows the varied responses given by patients for bother due to mass per say

<u>Patient bother related to urinary problems :</u>

There were 154 responses among the 69 of the 98 study patients who had urinary problems. The two most common urinary complaints were feeling of incomplete voiding (36; 23.38 %) and urgency to void (22; 14.29 %). Following are a sample of their responses:

" its so embarrassing to work among others with my urinary problems. I need to go so frequently to urinate because it feels so incomplete even after voiding"
" I am tired of my urine leakage and the smell of urine all the time"

Table 19: sample of the description of urinary problems as stated by patients in the study instrument

Description of urinary complaints	Number of such responses and proportion N= 154
Burning sensation during voiding	4 (2.59 %)
Difficulty in initiating voiding	18 (11.68 %)
Straining	6 (3.89 %)
Hesitancy in voiding	6 (3.89 %)
Poor stream of voiding	4 (2.59 %)
Need to push on the bulge in vagina to void	3 (1.94 %)
Have a feeling of obstruction while voiding	1 (0.64 %)
Have feeling of incomplete voiding	36 (23.38 %)
Have urgency to void	22 (14.29 %)
Have leakage of urine along with the urge to void	8 (5.19 %)
Have leakage of urine while coughing,straining or on carrying weights	15 (9.74 %)
Unable to void needing catheterization	2 (1.29 %)
Need to stand or change positions in order to void	13 (8.44 %)
Increased frequency of voiding	12 (7.79 %)
Having recurrent urinary infection	1 (0.64 %)
Having leakage of urine soon after voiding	2 (1.29 %)
Frustrating	1 (0.64 %)

Table 20: the varied responses for urinary problems obtained from patients in the study instrument

<u>Patient bother due to fecal problems :</u>

Out of the 98 study patients only 20 of them had problems with passing motions. There were 26 responses for patient bother in relation to fecal problems. The QOL of life score for fecal

complaints range from 20 to 90, with a median score of 50. The most common of all the responses in this symptom bother was " needing to strain for passing motions ". 12 responses out of 26 (46.15 %) belonged to this description. Following are a list of the responses obtained in this category of patient bother:

Description of patient bother	Number and proportion of such responses N= 26
Constipation	5 (19.23 %)
Need to strain to pass motions	12 (46.15 %)
Feeling of incomplete emptying of bowel	3 (11.53 %)
Passage of stools without control	3 (11.53 %)
Having sense of urgency to pass motions	1 (3.84 %)
Having burning sensation while passing motions	1 (3.84 %)
Need to change positions in order to pass motions	1 (3.84 %)

Table 21 : Responses obtained from patients for defeaction problems in the study instrument

Description of patient bother related to activity :

78 out of 98 study patients had problems in activity due to the prolapse. There were 148 responses of patient bother in this category. The QOL scores due to the affect of prolapse on activity ranged from 20 to 100, with a median score of 80. The most common response in this category was :

" I have problem walking because of this mass rubbing against my legs" there were 97 such responses accounting for 65.54 % of responses in this category.
"I am unable to cook because when I sit this mass rubs against the floor"
"I have problems going to work, because on carrying weights this mass comes out"
"I am unable to wash clothes because I feel uncomfortable due to this mass rubbing on the

floor”
“I cannot sit on hard surfaces because of this mass, as it makes me feel uncomfortable”

Table 22: sample of responses given by patients for affect on daily activity due to prolapse

Following are the list of descriptions of responses with the number and proportion of their occurrence:

Description of problems related to activity	Number and proportion of such responses N= 148
Unable to go to work due to this mass	12 (8.1 %)
Backache affecting work	4 (2.7 %)
Difficulty in sitting, standing, walking or bending	97 (65.54 %)
Pain in lower abdomen or heaviness affecting work	2 (1.35 %)
Unable to carry weights due to this therefore unable to go to work	6 (4.05 %)
Difficulty in doing day to day activities	22 (14.86 %)
Bilateral knee joint pain	1 (0.67 %)
Local discomfort which affects work	2 (1.35 %)
Generalized weakness	1 (0.67 %)
Frustrated	1 (0.67 %)

Table 23 : the varied responses obtained for affect on daily activities by patients

<u>Patient bother related to social life :</u>

Out of the 98 patients only 15 patients, had problems in this category. There were 23 responses given by these 15 patients in this category. Their affect on QOL scores ranged from 50 to 100. With a median score of 75. The most common response in this category was “ avoiding going out of home because of this mass”. There were 9 such responses out of the 23 responses (ie 39.1 %). The other responses are as follows:

Description of responses	Number and proportion of responses N= 23
"Avoiding going out of home due to the mass"	9 (39.1 %)
"Avoiding going out of home because of the urinary problems that makes me feel uncomfortable"	2 (8.69 %)
"avoiding going out because of the vaginal discharge and the bleeding per vaginum"	4 (17.39 %)
"avoiding going out because cannot sit for long"	2 (8.69 %)
"avoid travelling "	2 (8.69 %)
Depressed and frustrated due to the condition	4 (14.39 %)

Table 24: the varied responses obtained for affect on social life by patients

Description of patient bother in sexual life :

Out of the 98 study patients, 40 of them (40.81 %) were sexually active. Out of these 40 women who were sexually active only 17 (42.5 %) were abstaining from sexual activity due to the prolapse. 1 of these 17 women who were abstaining from sexual activity was because she was advised by a doctor to do so, although she had no problems during intercourse. The remaining 16 were avoiding intercourse due to the discomfort caused by the prolapse.

The most common response of patient bother in this category was "I have pain during intercourse". There were 10 such responses out of the 17 responses in this category. The other responses were as follows:

Description of patient bother	Number of proportion of response
Abstaining from intercourse as per the advice of a doctor	1 (5.88 %)
Pain during intercourse	10 (58.8 %)

Feeling inconvenient during intercourse due to the mass in vagina	1 (5.88 %)
Having a feeling of obstruction during intercourse due to the mass	5 (29.41 %)

Table 25: the varied responses of patients for affect of prolapse on sexual life

Ist Post operative follow up :

Out of the 71 patients who were followed up at 6 weeks. 65 of them (92.85 %) said that they were normal or better. But 5 of them (7.14 %) said they were either unhappy or not good at follow up.

Sample of the comments given by the 5 patients who were unhappy at 1st follow up are as follows:

"Pain in suture site" due to which had difficulty in walking and sitting.
"Lower abdomen pain and burning sensation on voiding"
"Having leakage of urine on coughing after surgery"
"Frustrated due to the pain in the suture site and burning sensation on voiding"

Table 26: sample of the comments given by patients at 6 weeks follow up

Although 65 patients of the 70 who were followed up at 6 weeks claimed to be normal or better, 18 of them still had some concerns.

On the whole during the 1st post operative follow up 23 of the 70 patients (32.85 %) had some problem which they wished would resolve. This was depicted also in the list of new hopes that they had mentioned during the interview. There were 33 new hopes. Of these 7 were related to urinary problems (ie 21.21 % of problems) and 5 were complaints of pain in the suture site (ie 15.15 % of problems)

2nd post operative follow up :

60 patients out of 98 were followed up at 3 months. Of them 57 patients (95 %) said they were either normal or much better. But 3 patients (5 %) were unhappy at the follow up. Of the 3 patients , 1 patient felt she had worsened as compared to before the surgery.

Reasons for dissatisfaction postoperatively in 3 patients were as follows :

" having increased tiredness now after the surgery"
"having persistent pain in the suture site due to which I am she having difficulty in sitting and walking associated with burning sensation on voiding" She had these problems even during the 1st follow up
"having persistent pain in the lower abdomen". Also noticed a swelling in the vagina while passing motions associated with pain while passing motions. I am scared of it coming back again."

Table 27: sample of comments of patients at 3 month follow up

Results of prioritization of patient specified problems preoperatively :

As part of the semi structured interview patients were asked to prioritize their self enlisted problems due to the prolapse, from 1-5 as per their severity. The 1st being the most bothersome.

It was noted that among the 1st priority, symptom relief was the most common 89 out of 98 patients (90.8 %). The rest of the patients placed activity related as their 1st priority ie. 9 out of 98 (9.18 %).

Following is the distribution of the top three priorities according to the various domains.

Domain distribution	1st priority N = 98	2nd priority N = 98	3rd priority N = 98
Domain 1 – symptom related	89 (90.8 %)	53 (54.08 %)	27 (27.55 %)
Domain 2 – activity related	9 (9.18 %)	37 (37.75 %)	34 (34.69 %)
Domain 3 – related to emotional life	0	0	2 (2.04 %)
Domain 4 – related to social life	0	0	0

Domain 5 – related to sexual life	0	1 (1.02 %)	2 (2.04 %)
Domain 6 – others	0	0	0

Table 28 : showing the distribution of the top three priorities of patients for seeking treatment according to the various domains

H) Comparison between the QOL scores obtained by the study instrument with the results from the validated questionnaire

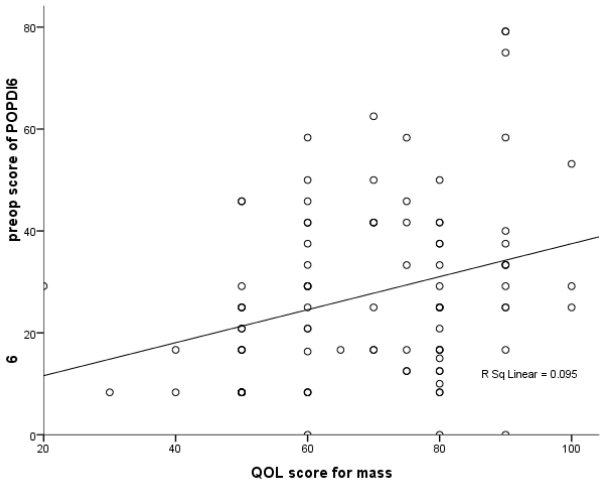
We assume that the QOL scores obtained for patient bother due to the mass, urinary problems and fecal problems need to be represented in the POPDI 20 score. Because the POPDI 20 score is a cumulative score of 3 subscales UDI 6, CRADI 8 and POPDI 6 which are for urinary, fecal and mass problems respectively.

We therefore looked at correlation between the scores obtained for each of these categories in our study instrument with the scores obtained in the validated questionnaires. The results are as follows :

Correlation between POPDI 6 and score for mass from the study instrument **:**

There was a significant correlation seen between the two using the Spearman's correlation.(r =0.309 and p= 0.002)

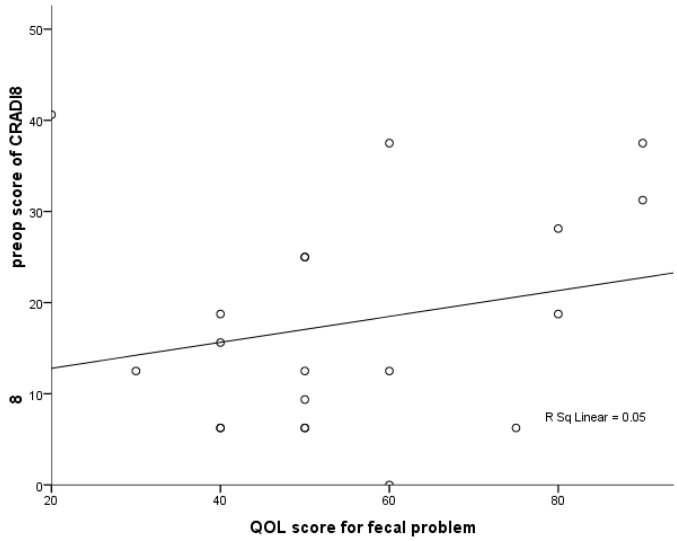
Scatter plot showing the distribution of the pre operative scores obtained for mass and the preoperative POPDI 6 scores:



graph 4: showing the scores for POPDI6 and the scores for mass as obtained in the study instrument.

Correlation between the scores obtained for patient bother due to fecal problems and the scores obtained for CRADI 8:

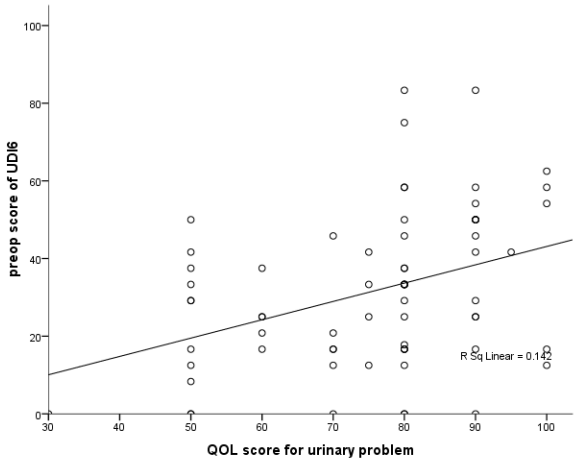
Only 20 patients had problems with defecation in the study instrument. The scores obtained showed no significant correlation using the Spearman's correlation. (r = 0.224 and p = 0.341)



graph 5: showing the scores obtained for fecal problems and the CRADI8 scores

Correlation between the pre operative scores obtained for urinary problems and the UDI 6 scores:

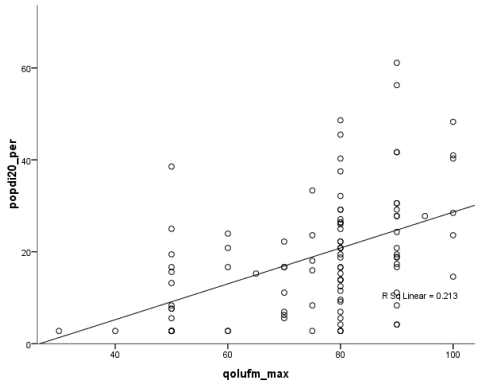
69 patients had bother due to urinary problems in the study instrument. Their scores showed a significant correlation with the pre operative UDI 6 scores using the Spearman's correlation. (r = 0.376 and p =0.001)



graph 6: showing the scores obtained for urinay problems and the UDI 6 scores

Correlation between the maximum scores obtained for mass , urinary and fecal related bother with the POPDI 20 scores:

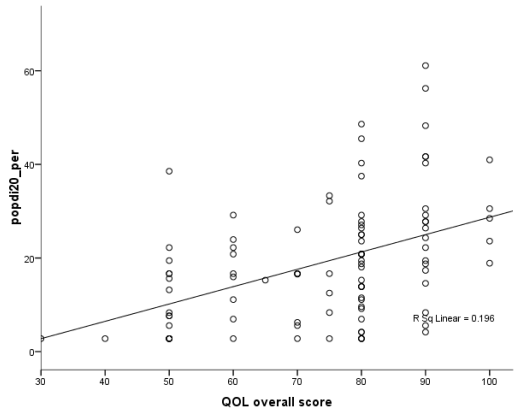
We also looked at the correlation between the maximum scores obtained for mass , urinary and fecal related bother with the POPDI 20 scores using the Spearman's correlation. This showed a significant correlation. (r = 0.462 and p = 0.000)



graph 7: showing the relation between the highest score obtained for mass,urinary or fecal problems with the POPDI20 score

Correlation between the overall scores for quality of life obtained in the study instrument with the POPDI 20 scores:

There was a significant correlation (r = 0.443 and p 0.000) between the POPDI 20 scores and the overall QOL scores obtained by the study instrument.

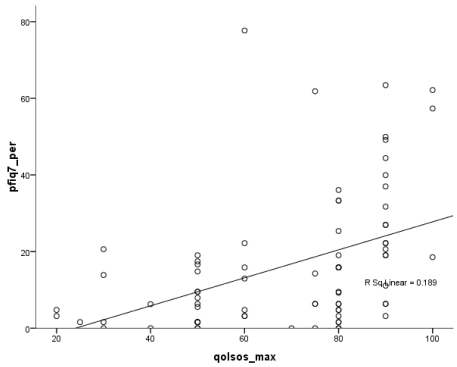


graph 8: relation between the over all affect on quality of life score by the study instrument with the POPDI 20 score

Correlation between the highest score obtained for QOL bother in the categories of activity, social life and sexual life in our study instrument with the PFIQ7 score.

Patient bother due to the mass, urinary or fecal problems can in turn affect their activity, emotions, social life and sexual life. We therefore looked for a correlation between the highest score obtained for QOL bother in the categories of activity, social life and sexual life in our study instrument with the PFIQ7 score. Using the pearson correlation, this was found to be significant.

(r= 0.434 and p 0.000)



graph 9: the relation between the highest scores obtained for social life, sexual life and activity in the study instrument with the pre operative PFI7 scores

	r value	p value
POPDI 6 with QOL score for mass	0.309	0.002
CRADI 8 with QOL score for fecal	0.224	0.341
UDI 6 with QOL score for urinary	0.376	0.001
POPDI 20 with overall QOL scores	0.443	<0.01
POPDI 20 with highest score between QOL scores obtained for mass, urinary and fecal bother	0.462	<0.01
PFIQ 7 with highest score between QOL scores for activity,	0.434	<0.01

social and sexual life bother		

Table 29: showing the significance of correlation between various scores of the validated questionnaires and the scores of the study instrument, as obtained by using Spearman's correlation.

Regression analysis:

With the scores obtained for the study instrument and the pre operative POPDI20, its subscales (POPDI6 , UDI6) and the PFIQ scores regression analysis was done to assess the predictability of the internationally used scores (POPDI6, UDI 6 subscales, POPDI20 scale and the PFIQ 7 scale).

The values obtained are as follows :

Variable	β	SE (standard error)	95%CI (confidence interval)	P value
POPDI 6 vs the score for mass affect	0.324	0.102	0.12 to 0.53	0.002
UDI6 vs the score for urinary affect	0.472	0.142	0.19 to 0.76	0.001
POPDI 20 vs the highest score between urine,fecal and mass affect	0.390	0.076	0.24 to 0.54	<0.01
PFIQ 7 vs the highest score between social, sexual and activity	0.365	0.087	0.19 to 0.54	<0.01
POPDI 20 vs overall qol score	0.371	0.077	0.22 to 0.52	<0.01

Table 30 : showing the results of the regression correlation between the condition specific questionnaires scores (POPDI6, UDI6 subscales and POPDI 20 , PFIQ7 scales) with the scores obtained for affect of mass, urine, overall qol score, affect on social life, sexual life and activity.

Note : regression correlation calculation not done for CRADI8 vs score for affect on fecal problem, since no statistically significant correlation obtained between the two using the Pearson's correlation.

Actual prediction equation :

The values obtained from the regression calculation can be used to predict the international validated scores POPDI 20 and PFIQ7 scores from the study questionnaire.

The formula used is :

$Y = (\alpha + \beta) X$

Y = the international validated score to be calculated

α= constant value

β= calculated using the regression correlation

X = the score obtained from the study instrument

Eg1. : POPDI 20 vs the highest score between urine, fecal and mass affect:

Using the formula above, the POPDI 20 for a patient can be calculated using the highest of the scores obtained between urine, fecal and mass affect in the study questionnaire as follows:

Popdi20 = -10.366+0.390 x (highest score between affect due to mass, urine, fecal problem)

Here -10.366 : the constant (α)

0.390 : beta value (β)

Eg 2 : PFIQ 7 vs the highest score between social, sexual and activity

Using the same formula give above, the PFIQ7 score can be calculated using the highest of the scores obtained between affect on activity, social life and sexual life in the study instrument as follows :

PFIQ7 score = α + 0.365 x(highest score between affect on social life, sexual life and activity)

Similarly, the validated questionnaire scores can be calculated using the above formula from the scores obtained in the study instrument. The POPDI 6 score can be calculated from the score obtained for mass related bother in the study instrument, UDI 6 score from score for problems related to urination, overall POPDI 20 score from the overall score for bother due to prolapse from the study instrument, the PFIQ7 score from the highest score of the activity related bother, bother in social and sexual life due to prolapse in the study instrument. The confidence interval for such calculated scores is specified in the table above.

Discussion :

In patients with pelvic floor dysfunction, outcomes can be measured in various ways including physical examination for restoration of normal anatomy, symptom resolution and the patient's quality of life.(2,6,8–13) A more objective outcome measurement is easy to assess and can be used easily in research for comparisons. But considering the WHO definition for health,(84) it is a multidimensional factor. It involves patient sensed measures of health which extends from physical function, role function, social, emotional and mental state, burden of symptoms and physical well-being. As emphasized earlier, pelvic organ prolapse has its impact on various aspects of life. And the reason for seeking medical attention, might be not just for the prolapse per say but it might be due to its affect on other aspects of life.

In this study we explored the expectations of our patients undergoing surgery for pelvic floor dysfunction using various tools. One was by asking them to enlist their 'hopes and fears' for the surgery pre operatively and assessing their achievement of hopes and resolution of fears post operatively. The other tool used was the study instrument, a semi structured interview, which was administered to patients to evaluate the effect of pelvic organ prolapse on various aspects of their life. They were asked to score the affect on the quality of life on a VAS scale as described in the methodology section. This was used as a basis for post operative follow up, during which their self listed bother in the various aspects of their life were assessed for improvement in their quality of life. Their self enlisted problems were also prioritized by them according to their perception of severity of bother. The standardized QOL condition specific questionnaires (POPDI 20 and PFIQ 7) were also administered to them both pre and post operatively.

A) Demographic details :

The study included 98 patients with a normal distribution of ages, ranging from 33 to 85 years. Most of our study patients (86%) belonged to SES classes 1 and 2. Only 10% and 3% of them belonged to SES classes 3 and 4, respectively. Although most of our patients were Tamil or Telugu speaking (68%), we still had a good representation of women from other spoken languages (Hindi and Bengali speaking were 31%).

The study group consisted of mainly post menopausal women (72.44%). They were mostly women with duration of prolapse of less than 5 years (63/98 ie. 64.28%). 22 of these 63 women (34.9%) had prolapse of less than 1 year duration.

Stages 3 and 4 prolapse together constituted 91% of our study patients as this was a study done on patients needing surgical correction.

B) Hopes and fears of patients undergoing surgery for pelvic organ prolapse:

Our study patients had more responses for hopes than for fears preoperatively. There were 207 responses for hopes as compared to 79 for fears. The mean number of hopes were also more than for fears (2.1 and 0.8 respectively).

67% of the hopes responses were symptom related. The second most commonly mentioned hopes was related to resumption of normal daily activity (19.32%). None of the study patients mentioned hopes related to emotions or social life. Only 1 response was obtained related to improvement in sexual life. Symptom resolution was seen to be the primary concern for more than 60% of our patients as seen in other studies(6).

The responses for fears were more generalized. They were no fears related to emotions, social and sexual life. Only 18.98% of responses for fears belonged to symptom resolution.

At the post operative follow up, only 2 of the 71 followed up at 6 weeks, had not resolved their fears nor achieved hopes in certain domains. These 2 patients had pre operative hope of getting back to normal work after surgery. But they did not achieve this hope at 6 weeks because one of them had pain in the suture site restricting activity and the other patient had to avoid work due to social pressures for rest in the post operative period. 80.2% (57 / 71) of patients followed up at 6 weeks had their hopes completely achieved and their fears completely resolved. Similarly at the 2 nd post operative follow up, 83.3% (50 out of 60) of patients claimed to have completely achieved their pre operative hopes and completely resolved fears.

14 / 71 in the 1st follow up and the 9/60 in the 2nd follow up who had partially resolved hopes and fears, were mainly related to symptom resolution. Interestingly there were new hopes or new fears mentioned by 23 of the 71 patients (32.3%) followed up at 6 weeks. The two most frequently encountered in the new hopes and new fears were concerning resolution of urinary problems and pain in the suture site. Similarly, only 10/60 (16.67%) of patients followed up at 3 months had enlisted new hopes or new fears.

Some of the patients who had persistently unachieved hopes during the post operative follow ups were due to unrealistic hopes unrelated to the pelvic surgery, such as joint pains and back ache 5/71 (7%). This emphasizes the need for preoperative counseling of patients and their care givers regarding the aim of the surgery. The fear of surgery due to a lack of understanding of the surgical procedure , was another commonly mentioned fear pre operatively. This can also be dealt with adequate interactive counseling.

C) The study instrument :

The semi structured interview used to collect information regarding patient bother in the

various aspects of life along with the extent of its affect the QOL by using the VAS scale was highly informative.

Since the interview was a semi structured one, although the questions were categorized, there was still space for the patient to be descriptive making the interview process more individualized and informative. Each individual patient could still express her bother without being restricted to a previously laid down definite structured questionnaire The condition specific QOL questionnaires give a broad understanding of the patients's condition but this in depth interview helps in understanding the needs of individuall patients as seen in some studies done earlier (7) This information of the description of patient bother and its severity in terms of a QOL score can help the treating physician in planning treatment, counseling regarding unrelated expectations and improve patient satisfaction.(2,6)

In the study it was noticed that among the patient's self enlisted 1st priority of 'bother', 90.8% were related to symptoms. And all the remaining 9.2% were related to increasing levels of daily activity.

This observation parallels the finding in the patient listed pre operative "hopes and fears". This observation for hopes and fears was similar among the various age groups studied, the various SES classes that were covered, the various stages of prolapse that were included and the duration of prolapse.

By these observations we can conclude that for our community, symptom resolution is perhaps the primary concern for treatment seeking as also seen in other communities(14). Second being "increasing activity"related to their daily activity. The others such as improvement in social life, emotional uplift and improvement in sexual life are not primary

concerns for our patients.

D) Results of POPDI 20 and PFIQ 7 questionnaires:

The scores obtained for POPDI 20 and PFIQ 7 in our patients pre operatively showed a significant correlation (using the Pearson's correlation) with the scores obtained in the semi structured interview. The scores of the POPDI6 and the UDI 6 showed significant correlation with the scores obtained in the study for affect due to mass and urinary problems preoperatively. The overall POPDI 20 score correlated significantly with the over all QOL score in the study as given by patients. This observation was seen for all results obtained as QOL scores with the study instrument except for the bowel symptoms and the CRADI 8 scores which did not show a significant correlation. Because only a small number of patients were affected with bowel complaints 20/98 (20.4%) no definite conclusion could be drawn from this study regarding fecal symptoms.

Using the regression calculation and the actual predictive equation the scores obtained from the study instrument could be used to predict the validated questionnaire scores significantly (except for the scores obtained for problems related to defecation and the CRADI 8 scores).

With this we can conclude that the study instrument is much more simple to administer than the international condition specific questionnaires for various reasons as given below:

a) The study instrument does not need validation to other languages
b) This study instrument can be easily administered
c) It has fewer simpler questions to administer than the international questionnaire
d) The study instrument gives the patient an opportunity to express ones views with openness. This makes it more individualized and descriptive.

e) As the scores obtained in the validated questionnaires POPDI 20 and PFIQ 7 were found to have statistically significant correlation with the scores in the study instrument (using the Pearson's correlation) the actual predictive equation and the values obtained using the regression analysis can be used to predict the POPDI20 and PFIQ7 scores significantly from the scores of the study instrument.

With the above findings we therefore conclude that the study instrument can be used for obtaining a better understanding of the expectations of our patients where administration of the validated condition specific questionnaires(POPDI20 and PFIQ7) is difficult due to language barriers and lack of validation in our community. This study instrument has the added advantage of being more individualized to patients and descriptive unlike the POPDI 20 and PFIQ7.

Conclusion :

Over the past decade there have been several international studies challenging anatomic restoration as the single outcome measure for pelvic reconstructive surgeries.

Various studies have investigated tools incorporating patient expectations in the outcome measures.

Our study was also based on the similar thinking that for patients with pelvic floor dysfunction, restoration of anatomy alone may not be completely ‘curative’. Patient’s expectations need to be considered while planning on treatment and measuring outcome.

The available validated condition specific QOL questionnaires are condition specific but lack individualization. They are reproducible and have a measurable result but lack descriptive component.

The study instrument that we have used has a qualitative and a quantitative component. The QOL scores obtained for the patient specified bother helps in making quantitative assessment of outcome. And the open ended semi structured interview allows individualizing treatment options. This can also aid in counseling patients and care givers for improving patient satisfaction by addressing to unrealistic expectations and fears in treatment opted for. Using the actual predictive equation the scores of the validated questionnaire can be significantly predicted from the scores obtained in the study instrument.

Limitations of the study:

1. The validated condition specific questionnaires were administered to the study population. For better comparative results it would be preferable to validate the questionnaires in our population, among the various languages of patients and re administer the same questionnaire by asking the patients to document their problems themselves.

2. The secondary objective of the study was to follow up a subset of patients post operatively at 6 weeks and 3 months. Although all the recruited patients consented for the follow up only 71 and 60 patients, of the 98 patients could be contacted for follow up at 6 weeks and 3 months respectively.

3. For better understanding of the concerns in the various SES classes of our community it would probably be better to design another study with equal distribution of patients in the various SES classes. Because in our study the proportion of patients varied in each SES class.

Recommendations :

1. In patients with pelvic floor dysfunction it is essential to incorporation a‘qualitative and quantitative assessment’ of their complaints pre operatively and their satisfaction post surgery.

2. Patient specified expectations and’ bother’ is to be used as a base line for planning on treatment for patients with pelvic floor dysfunction in order to improve their quality of life.

3. Adequate pre operative counseling of patients planned for pelvic reconstructive surgery is essential. This counseling should aim at building awareness in patients regarding the details of the surgery, the possible complications of the surgery and the specific expectations of patients then can be addressed by the surgery.

4. Pre operative counseling of patients and their care givers should also address their unrealistic expectations from the surgery. As this will help improve patient satisfaction.

5. In this study we have only laid the foundation for a ‘qualitative and quantitative assessment tool’ for patients with pelvic floor dysfunction, that could be used both pre operatively and post operatively for assessment of surgical outcome. The study instrument that we have used can be further refined and remodeled according to the needs and be used as a basis for further research in the same field in future.

ANNEXURES :

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Patient information sheet :

'pelvic organ prolapse' is a condition in which the uterus sags down into the vagina and along with it drags the adjacent organs. As part of our gynaecological evaluation here you have been diagnosed to have this condition and your treatment (surgery) has already been decided upon.

We in the department of Obstetrics and Gynaecology are trying to understand your hopes and fears as you await the surgery (the planned treatment) and after surgery we would like to assess the extent of achievement of your hopes and the resolution of your fears. This study will also help us to understand the effect of this condition on the quality of your life.

The study will include interviews with you and your family both before and after surgery at 6 weeks and 3 months. Your participation in this study will not, in any manner, affect either the type or the quality of treatment offered here. No monetary benefits or any other incentives will be provided for participating in the study.

The assessment of your responses will help us understand yours concerns and fears and possibly help our patients who are undergoing surgery for 'pelvic organ prolapse'. We hope that this study will help us in improving the quality of our care provided to similar patients.

Consent form :

"understanding the hopes and fears of patients undergoing surgery for pelvic organ prolapsed"

This study is done purely for research purpose and is aimed at understanding the hopes and fears of patients undergoing surgery for pelvic organ prolapsed in our hospital. Your identity as well as your answers will be kept confidential. Your answers will have no bearing on the type or quality of care given. This study is done for purely academic purpose to help us understand our patients concerns better. Your kind co-operation and participation is of utmost importance in this study.

- ✓ Strict confidentiality will be maintained regarding the study participation and your answer given
- ✓ Your answers will not have any bearing on the type or quality of care given
- ✓ No monetary or material incentive is provided for participation in this study
- ✓ Participation is purely voluntary
- ✓ Kindly ask questions and clear doubts before participating in the study

Please let us know if you will be willing to either come to the hospital or be available for follow up as part of the study at 6 weeks and 3 months following the surgery.

I _____ confirm that I have read and understood the information sheet and have had the opportunity to clear my doubts.

I understand that my participation is purely voluntary.

I understand that the ethics committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to this study even if I withdraw from the study during the course of it. I agree to this access. However, I understand that my identity will not be revealed to any third party unrelated to the study.

I agree not to restrict the use of any data (or) results that arise from this study provided such a use is only for a scientific purpose.

I agree to take part in the above study.

Signature (or) thumb impression of subject _____ date _____

Signature of investigator _____ date _____

Signature (or) thumb impression of witness _____ date _____

Pelvic organ prolapse hopes and fears survey:

Preoperative Questionnaire : **Serial No** **Hospital no :**
OG Unit :

Name : Age : Education : Occupation :

Husband's name : Age : Education : Occupation :

Languages spoken

Languages that can be a. read

b. written:

How many family members live in your house: < 5 / >5

Do you stay in a joint family :

How many children do you have :

Where were the deliveries conducted:

Did you have any problems during the delivery:

How much is the net income of your family in a month:

Who is the main earning member of your family:

You have now come for prolapse surgery, can you tell me, when did you 1st notice the prolapse and what were your problems at the beginning.

Problems	domain

1.Have your symptoms worsened over time from initially noticing the prolapse to the present

Can you score the severity of your present symptoms as perceived by you in the past 2 months over a scale of 1-100:

Probem with score[VAS]	domain

2. Do you have any problems with passing urine:

If yes can you describe what the problem is:

Problem with score [VAS]	domain

Can you please score the severity of your urinary symptoms as perceived by you in the past 2 months on a scale of 1-100:

3. Do you have problems with passing motions or flatus:

If yes could you please describe it:

Problem with score [VAS]	domain

Can you please score the severity of your fecal symptoms as perceived by you in the past 2 months on a scale of 1-100:

4. Do you have any concerns in you day to day activities due to this gynec condition:

If yes can you please describe it:

Problem with score [VAS]	domain

Can you score the the severity or difficulty caused in your day to day life due to this gynec condition as perceived by you in the past 2 months on a scale of 1-100:

5. Does this gynec condition affect you social life:

If yes, can you please describe it:

Problem with score [VAS]	domain

Can you please score the the severity of the hinderance in your social life due to this gynec condition as perceived by you in the past 2 months from 1-100:

6 a.Are you sexually active

b. Are you are abstaining or experiencing sexual difficulties due to the prolapse

7 If the prolapse has affected your sexual life score the severity of the effect describing the problem ,as perceived by you on a score of 1-100 :

Problem with score [VAS]	Domain

In the past 1 month have you had any other specific difficulties due to the prolapse:

Problem with score	Domain

8. If you were to spend the rest of your life with your prolapse condition just the way it is now,
how would you feel about that?[QOL]
score the severity of the effect as perceived by you on a score of 1-100 :

What is the order in which you would like to place the above problems, the first being the most worrying of all.

Problem	Domain as previously asssigned

Can you now list your hopes regarding the surgery for prolapse that you are planned to undergo, in the order of priority, with the first being the most important.

Hopes	Domain

Do you have any fears regarding the surgery :

How would you arrange the above fears the first being the most worrying of all

Fears	Domains

Did you have any hinderances or problems in obtaining medical attention for your gynec problem?

What made you make this decision of seeking treatment in this hospital:

How does your family feel about this gynec problem:

M**enstrual history** :

Menopause attained : Y / N If Y, No. of years of menopause :

Examination:

a) Neurological examination :
   1. Perianal sensation
   2. Anal sphincter tone
   3. Anal wink reflex

b) Per Speculum examination : cervix
   Vagina

c) Stress Test : Yes / No
   Supine
   Standing

d) Occult SUI Yes / No

Per Vaginal examination :

e) POP-Q

Aa	Ba	C
Gh	Pb	Tvl
Ap	Bp	D

e. ordinal stage assigned:

f) Per Rectal examination : A. sphincter tone

g) rectocele

Diagnosis :
Date of surgery :
Surgery performed :
Intraoperative complication :

We would like to contact you during the post operative period after 6 weeks and 3 months. Would you be able to come in person:

Contact address : Phone number : email :

Pelvic organ prolapse Hopes and fears survey :

Postoperative assessment questionnaire : Patient serial No : Interview no:

Patients name: **Duration from surgery :**

Date of surgery :

Surgery performed :

How are you after the surgery :

During the preoperative interview you had mentioned the following as your hopes and fears with regards to the surgery:

Hopes	Domain as assigned earlier	Fears	Domain as assigned earlier

Have you had any new hopes and fears now with regards to the surgery apart from what you had mentioned earlier during your pre operative period :

New hopes	Domain	New fears	Domain

Could you please score the achievement of your hopes on a scale of 1-100:

Hopes mentioned	Achievement score	Domain as assigned earlier

Could you please score the resolution of your fears on a scale of 1-100 :

Fears	Score for resolution of fears	Domain as assigned earlier

In the previous interview following were your problems due to the prolapse, each of which you had then scored its severity on a scale of 1 – 100.

Now that you have undergone surgery for the prolapse condition, can you please, now score the present severity of the above mentioned complaints on a scale of 1-100.

Problems mentioned preoperatively	Domain as assigned earlier	Current score of problem severity

Worst aspect of the surgery (*statement*)

_____

Best aspect of the surgery (*statement*)

_____

Were you prepared for surgery ? (Yes / No)

If ‘no’ then why:

Were you prepared for discharge ? (Yes / No)

If ‘no’ then why:

Overall satisfaction (expressed as percentage of 100% satisfied)

Reason for not being 100% satisfied (*statement*)

_____

Patients global impression on severity :

How would you describe your overall pelvic floor symptoms before surgery ?

- Normal
- Mild
- Moderate
- Severe

Patients global impression of improvement :

How would you describe your overall pelvic condition now compared to what it was before surgery ?

- Very much better
- Much better
- A little better
- No change
- A little worse
- Much worse
- Very much worse

Center for Female Continence PFDI-20

PT INITIALS_____**DOB**_____**DATE**_____
I.D. Number_____ **Research Site**_____

Pre ☐, **3 mo**☐, **6mo**☐, **12 mo**☐, **24 mo**☐, **36 mo**☐, **60 mo**☐

POPDI-6

1. Usually experience ***pressure*** in the lower abdomen?

☐ No ☐ Yes If yes, how much does it bother you?

Not at all	Somewhat	Moderately	Quite a bit	
☐	☐	☐	☐	Score

2. Usually experience ***heaviness or dullness*** in the pelvic area?

☐ No ☐ Yes If yes, how much does it bother you?

Not at all	Somewhat	Moderately	Quite a bit	
☐	☐	☐	☐	Score

2. Usually have a bulge or something falling out that you can see or feel in your vaginal area?

☐ No ☐ Yes If yes, how much does it bother you?

Not at all	Somewhat	Moderately	Quite a bit	
☐	☐	☐	☐	Score

3. Ever have to push on the vagina or around the rectum to have or complete a bowel movement?

☐ No ☐ Yes If yes, how much does it bother you?

Not at all	Somewhat	Moderately	Quite a bit	
☐	☐	☐	☐	Score

4. Usually experience a feeling of incomplete bladder emptying?

☐ No ☐ Yes If yes, how much does it bother you?

Not at all	Somewhat	Moderately	Quite a bit	
☐	☐	☐	☐	Score

6. Ever have to push up on a bulge in the vaginal area with your fingers to start or complete urination?

☐ No ☐ Yes If yes, how much does it bother you?

Not at all	Somewhat	Moderately	Quite a bit	
☐	☐	☐	☐	Score

POPDI-6 Total **x 25 =**

PFDI-20

P.I._____ DOB_____ Date_____

CRADI-8

7. Feel you need to strain too hard to have a bowel movement?
☐ No ☐ Yes If yes, how much does it bother you?
Not at all Somewhat Moderately Quite a bit
☐ ☐ ☐ ☐ Score

8. Feel you have not completely emptied your bowels at the end of a bowel movement?
☐ No ☐ Yes If yes, how much does it bother you?
Not at all Somewhat Moderately Quite a bit
☐ ☐ ☐ ☐ Score

9. Usually lose stool beyond your control if your stool is well formed?
☐ No ☐ Yes If yes, how much does it bother you?
Not at all Somewhat Moderately Quite a bit
☐ ☐ ☐ ☐ Score

10. Usually lose stool beyond your control if your stool is loose?
☐ No ☐ Yes If yes, how much does it bother you?
Not at all Somewhat Moderately Quite a bit
☐ ☐ ☐ ☐ Score

11. Usually lose gas from the rectum beyond your control?
☐ No ☐ Yes If yes, how much does it bother you?
Not at all Somewhat Moderately Quite a bit
☐ ☐ ☐ ☐ Score

12. Usually have pain when you pass your stool?
☐ No ☐ Yes If yes, how much does it bother you?
Not at all Somewhat Moderately Quite a bit
☐ ☐ ☐ ☐ Score

13. Experience a strong sense of urgency and have to rush to the bathroom to have a bowel movement?
☐ No ☐ Yes If yes, how much does it bother you?
Not at all Somewhat Moderately Quite a bit
☐ ☐ ☐ ☐ Score

14. Does par of your bowel ever bulge outside the rectum during or after a bowel movement? ☐ No ☐ Yes If yes, how much does it bother you?
Not at all Somewhat Moderately Quite a bit Score
☐ ☐ ☐ ☐

CRADI-8 Total x 25=

UDI-6

15. Usually experience frequent urination?

☐ No ☐ Yes If yes, how much does it bother you?

Not at all	Somewhat	Moderately	Quite a bit	
☐	☐	☐	☐	Score

16. Usually experience urine leakage associated with a feeling of urgency, i.e. i.e. a strong sensation of needing to go to the bathroom?

☐ No ☐ Yes If yes, how much does it bother you?

Not at all	Somewhat	Moderately	Quite a bit	
☐	☐	☐	☐	Score

17. Usually experience urine leakage with coughing, laughing, or sneezing?

☐ No ☐ Yes If yes, how much does it bother you?

Not at all	Somewhat	Moderately	Quite a bit	
☐	☐	☐	☐	Score

18. Usually experience small amounts of urine leakage (small drops of urine)?

☐ No ☐ Yes If yes, how much does it bother you?

Not at all	Somewhat	Moderately	Quite a bit	
☐	☐	☐	☐	Score

19. Usually experience difficulty emptying your bladder?

☐ No ☐ Yes If yes, how much does it bother you?

Not at all	Somewhat	Moderately	Quite a bit	
☐	☐	☐	☐	Score

20. Usually experience *pain or discomfort* in the lower abdomen or genital region?

☐ No ☐ Yes If yes, how much does it bother you?

Not at all	Somewhat	Moderately	Quite a bit	
☐	☐	☐	☐	Score

UDI-6 Total x 25 =

Scale scores: Obtain the mean value of all of the answered items within the corresponding scale (possible value 0 – 4) and then multiply by 25 to obtain the scale score (range 0 – 100). Missing items are dealt with by using the mean from answered items only.

PFDI-20 Summary Score: Add the scores from the 3 scales together to obtain the summary score (range 0 – 100).

POPDI-6 _____
CRADI-8 _____
UDI-6 _____

PFDI-20 SCORE _____

PT INITIALS_____ DATE_____
I.D. Number_____ Research Site_____

Pre ☐, 3 mo☐, 6mo☐, 12 mo☐, 24 mo☐, 36 mo☐, 60 mo☐

Pelvic Floor Impact Questionnaire—short form 7

Instructions: Some women find that bladder, bowel, or vaginal symptoms affect their activities, relationships, and feelings. For each question place an **X** in the response that best describes how much your activities, relationships, or feelings have been affected by your bladder, bowel, or vaginal symptoms or conditions **over the last 3 months.** Please make sure you mark an answer in **all 3 columns** for each question.

How do symptoms or conditions in the following usually affect your	*Bladder or urine*	*Bowel or rectum*	*Vagina or pelvis*
1. Ability to do household chores (cooking, laundry housecleaning)?	☐Not at all ☐Somewhat ☐Moderately ☐Quite a bit	☐Not at all ☐Somewhat ☐Moderately ☐Quite a bit	☐Not at all ☐Somewhat ☐Moderately ☐Quite a bit
2. Ability to do physical activities such as walking, swimming, or other exercise?	☐Not at all ☐Somewhat ☐Moderately ☐Quite a bit	☐Not at all ☐Somewhat ☐Moderately ☐Quite a bit	☐Not at all ☐Somewhat ☐Moderately ☐Quite a bit
3. Entertainment activities such as going to a movie or concert?	☐Not at all ☐Somewhat ☐Moderately ☐Quite a bit	☐Not at all ☐Somewhat ☐Moderately ☐Quite a bit	☐Not at all ☐Somewhat ☐Moderately ☐Quite a bit
4. Ability to travel by car or bus for a distance greater than 30 minutes away from home?	☐Not at all ☐Somewhat ☐Moderately ☐Quite a bit	☐Not at all ☐Somewhat ☐Moderately ☐Quite a bit	☐Not at all ☐Somewhat ☐Moderately ☐Quite a bit
5. Participating in social activities outside your home?	☐Not at all ☐Somewhat ☐Moderately ☐Quite a bit	☐Not at all ☐Somewhat ☐Moderately ☐Quite a bit	☐Not at all ☐Somewhat ☐Moderately ☐Quite a bit
6. Emotional health (nervousness, depression, etc)?	☐Not at all ☐Somewhat ☐Moderately ☐Quite a bit	☐Not at all ☐Somewhat ☐Moderately ☐Quite a bit	☐Not at all ☐Somewhat ☐Moderately ☐Quite a bit
7. Feeling frustrated?	☐Not at all ☐Somewhat ☐Moderately ☐Quite a bit	☐Not at all ☐Somewhat ☐Moderately ☐Quite a bit	☐Not at all ☐Somewhat ☐Moderately ☐Quite a bit
Total	**x 100**	**x 100**	**x 100**

Scoring the PFIQ-7: =

All of the items use the following response scale:

0, Not at all; 1, somewhat; 2, moderately; 3, quite a bit **PFIQ-7 Score _____**

Scales:

Urinary Impact Questionnaire (UIQ-7): 7 items under column heading "Bladder or urine"
Colorectal-Anal Impact questionnaire (CRAIQ-7): 7 items under column heading "Bowel / rectum"
Pelvic Organ Prolapse Impact Questionnaire (POPIQ-7): Items under column "Pelvis / Vagina"
Scale Scores: Obtain the mean value for all of the answered items within the corresponding scale (possible value 0 – 3) and then multiply by (100/3) to obtain the scale score (range 0-100). Missing items are dealt with by using the mean from answered items only.
PFIQ-7 Summary Score: Add the scores from the 3 scales together to obtain the summary score (range 0-300).

ser	stupart	ses	age	dura	qolscr	n1stsymp	dom	prosym1	prosy	prosym2	prosy	qol	urinesymp1	urin	urinesym2	urine	urinesym3	urine
1	1	1	67	96	30	difficulty in sitting down	2	difficulty ir	2	difficulty in	2	0						
2	1	1	65	24	50	mass descending per vagina	1	occasional	1	rubs agains	2	0						
3	1	1	50	24	80	mass descending per vagina	1	lower abdc	1	difficulty in	2	50	incomplete	1	urgency	1	dribbling o	1
4	1	1	51	36	20	mass descending per vagina	1	difficulty ir	2			80	incomplete	1	increased f	1		
5	1	2	44	204	50	mass descending pv	1	inc in size c	1	low back ac	1	90	incomplete	1	splinting	1	urgency	1
6	1	1	62	24	50	mass descending per vagina	1	mass felt d	1			60	difficulty in	1				
7	1	3	45	6	75	mass descending per vagina	1	difficulty ir	2	difficulty in	2	75	difficulty in	1	incomplete	1		
8	1	2	50	120	80	mass descending per vagina	1					90	urinary rete	1				
9	1	2	68	12	100	mass descending per vagina	1	backache	1	blood stain	1	0						
10	1	2	69	6	80	mass descending per vagina	1	difficulty ir	2			50	increased f	1	difficulty in	1		
11	1	2	52	10	80	mass descending per vagina	1	increase in	1	difficulty in	2	0						
12	1	1	54	48	50	mass descending per vagina	1	mass desce	1			70	increased f	1	recurrent u	1		
13	1	2	40	12	75	mass descending per vagina	1	mas descer	1			60	poor strear	1				
14	1	3	56	120	90	mass descending per vagina	1	mass desc	1	occasionall	1	0						
15	1	3	55	6	90	mass descending per vagina	1	mass desce	1	lower abdc	1	90	difficulty in	1				
16	1	1	49	36	90	mass descending per vagina	1	mass desce	1	difficulty in	2	0						
17	1	2	60	4	75	mass descending per vagina	1	mass desce	1			50	burning on	1	increased f	1		
18	1	1	55	12	50	mass descending per vagina	1	mass desce	1			0						
19	1	2	64	4	50	mass descending per vagina	1	mass desce	1			0						
20	1	2	65	36	80	mass descending per vagina	1	mass desce	1			80	urgency	1	leaking on	1		
21	1	2	64	3	80	mass descending per vagina	1	mass desce	1			0						
23	2	2	57	36	60	mass descending per vagina	1	gradually ir	1	vaginal disc	1	75	urgency	1	urine leaka	1	urge incont	1
24	1	4	52	12	90	mass descending per vagina	1	increase in	1			0						
25	1	2	55	108	50	increase in size of mass des	1	increase in	1	post menop	1	0						
26	1	2	69	60	50	mass descending per vagina	1	gradually ir	1	low back ac	1	90	increased f	1	urgency	1	leakage of	1
27	1	2	33	120	80	increase in size of mass des	1	increase in	1			0						
28	1	4	62	48	90	increase in size of mass des	1	blood stain	1			90	urine leaka	1	urgency	1	incomplete	1
29	1	1	50	156	80	increase in size of mass des	1	increase in	1	pain in low	1	0						
30	1	1	58	24	30	mass descending per vagina	1	increase in	1			30	incomplete	1				
31	1	2	52	300	40	mass descending per vagina	1	increase in	1			0						
32	1	2	50	18	70	mass descending per vagina	1	increase in	1	bloodstain	1	80	increased f	1	urine leaka	1		
33	1	2	43	12	70	increase in size of mass des	1	increase in	1			60	incomplete	1	urgency	1	increased f	1
34	1	2	78	12	70	increase in size of mass des	1	mass desce	1	difficulty in	2	80	problem wi	1	urgency	1	incomplete	1
35	1	1	45	84	90	mass descending per vagina	1	mass desce	1	dragging se	1	0						
36	1	1	64	9	80	increase in size of mass des	1	increase in	1	discharge F	1	75	urgency	1	incontinen	1		
37	1	2	39	72	50	mass descending per vagina	1	increase in	1			80	urinary urg	1	urgency	1	dysuria	1
38	1	2	56	36	60	mass descending per vagina	1	increase in	1			90	urinary urg	1	increased f	1	incomplete	1
40	1	2	48	96	60	mass descending per vagina	1	increase in	1	low bacjkac	1	70	increased f	1				
42	1	2	60	240	90	mass descending per vagina	1	increase in	1	blood stain	1	70	incrreased	1	incomplete	1		
43	1	1	43	36	60	mass descending per vagina	1	increase in	1			80	diff in voidi	1	poor strear	1	incomplete	1
44	1	2	57	12	60	mass descending per vagina	1	inrease in s	1			60	increase in	1	incomplete	1		
45	1	2	56	12	50	mass descending per vagina	1	increase in	1			50	diff in initia	1				
46	1	2	42	96	80	mass descending per vagina	1	increase in	1			80	urgency to	1	urinary leal	1	incomplete	1
47	1	1	40	120	60	mass descending per vagina	1	increase in	1			0						
48	1	3	65	60	90	mass descending per vagina	1	increase in	1			50	incomplete	1	increased f	1		
49	1	2	54	12	50	mass descending per vagina	1	increase in	1			0						
50	1	2	42	120	75	mass descending per vagina	1	increase in	1	low back ac	1	##	dysuria, str	1	splinting	1	incomplete	1
51	1	3	40	12	90	mass descending per vagina	1	increase in	1			90	diff in voidi	1				
52	1	2	33	120	75	increase in size of mass des	1					0						
53	1	2	43	18	65	increase in size of mass des	1	increase in	1	lower abdc	1	0						
54	1	2	54	72	60	mass descending per vagina	1	gradually ir	1	vaginal disc	1	80	incomplete	1	straining, p	1	splinting	1
55	1	2	35	96	80	mass descending pv 3 mths	1	increase in	1			0						
56	1	2	60	6	90	increase in size of mass des	1	increase in	1			##	difficulty in	1	poor strear	1		
57	1	4	63	240	80	mass descending per vagina	1	increase in	1			80	diff in voidi	1				
58	1	2	64	3	50	mass descending per vagina	1	mass desce	1			0						
59	1	1	70	12	70	mass descending per vagina	1	increase in	1			0						
60	1	2	50	24	60	mass descending per vagina	1	increase in	1			80	urinary leal	1	frequant ur	1	incomplete	1
62	1	2	47	72	50	mass descending per vagina	1	increase in	1			50	hesitancy ir	1				
63	1	1	72	24	80	mass descending per vagina	1	increase in	1			50	difficulty in	1				
64	1	1	48	12	80	increase in size of mass des	1	increase in	1	feels "yuki"	3	0						
65	1	2	60	24	60	mass descending per vagina	1	mass desce	1			80	urgency	1	incontinen	1	incomplete	1
66	1	1	71	96	90	mass descending per vagina	1	increase in	1			90	incomplete	1	post void d	1		
67	1	2	63	3	70	mass descending per vagina	1	low back ac	1	increase in	1	95	increased f	1	poor strear	1	need to pre	1
68	1	3	50	144	70	mass descending per vagina	1	increase in	1	lower abdc	1	80	diff in voidi	1	leaking of u	1		
69	1	2	70	2	50	mass descending per vagina	1	bleeding pe	1	mass desce	1	90	urinary diff	1	urinary rete	1		

70	1	3	50	120	90	mass descending per vagin	1	increase in	1	low back a	1	##	urinary urg	1	hesitancy	1	need to sta	1
71	1	3	45	5	90	mass descending per vagin	1	increase in	1	pain in the	1	90	difficulty in	1	slow strear	1	dysuria	1
72	1	3	45	24	50	mass descending per vagin	1	increase in	1	bleeding p	1	50	strain to vo	1	diff in voidi	1	spinting to	1
73	1	1	64	120	60	mass descending per vagin	1	increase in	1			80	increased f	1	urgency	1	leakage of	1
74	1	2	56	36	100	increase in size of mass des	1					##	feeling of c	1	can void or	1	frustrating	3
75	1	1	61	2	50	bleeding per vaginum	1					0						
76	1	2	51	4	60	mass descending per vagin	1	mass desce	1	lower abdc	1	90	difficulty in	1	poor strear	1	strain to vo	1
77	1	2	38	216	80	mass descending per vagin	1	increase in	1	low back a	1	0						
78	1	2	60	36	80	mass descending per vagin	1	mass desce	1	bleeding p	1	0						
79	1	2	33	3	75	mass descending per vagin	1	mass desce	1			75	strain whil	1	incomplete	1		
80	1	2	58	36	60	mass descending per vagin	1	increase in	1			60	difficulty in	1	urgency of	1		
81	1	1	66	24	50	mass descending per vagin	1					70	incomplete	1				
82	1	1	46	10	75	mass descending per vagin	1					80	need to str	1	hesitancy	1	incomplete	1
83	1	2	85	48	0	mass descending pv for 25	1					50	urinary lea	1	urinary leal	1	increased f	1
84	1	2	53	360	60	increase in size of mass des	1	low back a	1	increase in	1	80	hesitancy i	1	need to sta	1		
85	1	2	37	168	80	gradually increasing mass d	1	gradual inc	1			80	difficulty in	1	incomplete	1		
86	1	2	59	6	50	mass descending per vagin	1					70	urgency	1	incontinen	1	incontinen	1
87	1	1	48	240	50	mass descending per vagin	1	increase in	1			70	incomplete	1	increased f	1		
88	1	2	40	120	50	gradually increasing size of	1					50	increased f	1	incomplete	1		
89	1	2	34	132	70	mass desending per vaginu	1	increase in	1	low back a	1	90	urgency	1	leakage on	1	need to rec	1
90	1	2	64	5	80	increase in size of mass des	1	increase in	1	discharge p	1	80	difficulty in	1	poor strear	1		
91	1	2	64	60	50	mass descending per vagin	1	vaginal disc	1	mass desce	1	0						
92	1	1	50	12	60	mass descending pv- had pe	1	increase in	1	discomfort	1	80	incomplete	1	increased f	1	hesitancy	1
93	1	1	51	24	60	mass descending per vagin	1	mass desce	1			80	increased f	1	urgency	1	leakage of	1
94	1	1	68	24	40	mass desending per vaginu	1	lower abdc	1	mass desce	1	50	incomplete	1				
95	1	1	60	4	50	mass desending per vaginu	1	increase gr	1			0						
96	1	2	45	240	90	increase in size of mass des	1	abdominal	1	increase in	1	90	straining fc	1	splinting to	1	incomplete	1
97	1	1	40	6	50	mass descending per vagin	1	increase in	1			0						
98	1	2	70	12	100	mass descending per vagin	1	increase in	1			##	poor strear	1	diff in initia	1	incomplete	1
99	1	3	42	120	70	mass descending per vagin	1	increase in	1	dragging se	1	80	need to pu	1	urgency	1	incomplete	1
100	1	2	65	12	80	mass descending per vagin	1	increase in	1	discharge p	1	80	urgency					
101	1	2	36	6	80	mass descending per vagin	1					80	increased frequ					
102	1	2	55	12	80	mass descending per vagin	1	increase in	1			90	hesitancy	1	incomplete	1	urinary leak	1